**University of Alberta**

*Policy Challenge in Nanotechnology :A Canadian Perspective*

by

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## ABSTRACT

Nanotechnology is an exciting new area involving the work of many disciplines. As such, there is obvious challenge to existing legal frameworks due to the novel nature of this technology. It is possible to draw on past experiences with technology in order to inform this debate. This thesis argues that there is wide ranging policy challenge created by this new technology. The areas of patent policy challenge, as well as clinical and legal challenge are emphasized as areas that are closely related to the innovation process in Canada. This thesis offers recommendations as to how some of these novel challenges could be addressed.

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# Chapter 1 Introductory Chapter: Definitions and Overview of Nano Legal Landscape in Canada

## 1. Introduction

Few technologies have generated as much hype, excitement and attention as nanotechnology. It has become a major theme of pop culture, evidenced through avenues such as film and literature. The futuristic fascination with "molecular nanotechnology" has created much of the nanotech hype.[1] Arguably, there are dangers in "overhyping research and losing public trust." [2] However, given that progress is inevitable, establishing a societal dialogue is essential as we move forward. One should consider the wide ranging opinions on the technologies future including both "utopian" and "dystopian" visions.[3] There are varying concerns over "environmental impacts, health and safety, control and ownership", as well as a variety of novel ethical questions.[4] Such issues have led groups, such as the Winnipeg based ETC Group, to call for a "global moratorium on the manufacture of nanomaterials"[5] Contrarily, research indicated a variety of positive views. The views included the diverse nature of

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[1] Alexander H. Arnall, *Future Technologies, Today's Choices – A report for the Greenpeace Environmental Trust*,(London:Greenpeace Environmental Trust, 2003) at 36 Online: <www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/5886.pdf>; According to research by Caulfield & Bubela there are suggestions that "inaccurate or exaggerated reporting can have an adverse impact on public understanding, creating unwarranted hope or fears, and the development of informed policies". – Timothy Caulfield and Tania Bubela, "Media Representations of Genetic Discoveries: Hype in the Headlines"(2004) 12 Health law Review at 53.

[2] Bryn Williams-Jones, "A Spoonful of Trust Helps the Nanotech Go Down", (2004) 12 Health Law Review 10 at 10.

[3] Jean-Pierre Dupuy, "Complexity and Uncertainty A Prudential Approach to Nanotechnology" (Paper prepared for Mar 1-2, 2004 meeting of the Directorate-General for Health and Consumer Protection of the European Commission, "Mapping out Nano-risks") at 72

[4] Edna F. Einsiedel & Greg McMullen, "Stakeholders and Technology: Challenges for Nanotechnology" (2004) 12 Health law Review 5 at 5.

[5] ***Supra*** note 1 at 43.

nanotechnology "applications and products", the interdisciplinary nature of the nano and the dangers of misuse as a result of a ban.[6]

Notably, nanotechnology is a major area of academic research. Nanotechnology involves the work of many disciplines including chemists, physicists, biologists, cognitive scientists, electrical engineers and material scientists.[7] At the University of Alberta, major initiatives such as NINT[8] (National Institute of Nanotechnology) are illustrative of such progress. Recent advances in the field of nanotechnology at the University of Alberta include new diagnostics that enable efficient and effective diagnosis of disease. Issues relevant to such diagnostics are examined throughout the paper.

In comparison with other jurisdictions, it appears that Canada has done little to accommodate or address ethical, legal and social issues in nanotechnology. In fact, both Europe and the United States are much more advanced in coordinating initiatives that at

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[6] ***Supra*** note 1 at 43.

[7] Scientists from numerous areas are affected and communication among these sectors is increasingly necessary. ETC Group "Nanotech ungooed! Is the Grey/Goo Brouhaha the Industry's second blunder?" *ETC Group Comminique Issue #80* (July/ August 2003) at 2. Online:< www.etcgroup.org/article.asp?newsid=399> Last Accessed: January 2006

[8] Recent news includes, "The National Institute for Nanotechnology (NINT) at the University of Alberta received a $3.8 million investment ... from Western Economic Diversification Canada for its Innovation Centre devoted to attracting and facilitating commercialization of nanotechnology and related technologies." - Scott Lingley, "NINT receives $3.8 million for Innovation Centre" *Express News* (12 October, 2005); Examples of other projects at the U of A include what is "believed to be the first commercial application of nanotechnology". This application was a silver particle infused Acticoat bandage developed by Dr. Robert Burrell.
Online: <http://www.abheritage.ca/abinvents/inventors/robertburrell_biography.htm; Another example is the 2005 work of Dr. Robert Wolkows team that have "demonstrated that a molecule could be controllably charged by a single atom while all adjacent atoms remained neutral...The molecule thus becomes a nanotech version... of a common transistor" - Glenn Martin, "Scientists utilize molecule as basic transistor, Breakthough could be important for future computers" *San Francisco Chronicle* (2 June 2005) Online: <http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2005/06/02/MNGUOD1V1P1.DTL>

least investigate the pressing societal and ethical issues.[9] Therefore, an overview of basic legal and social issues in Canada is a valid thesis topic.

This thesis highlights areas that government needs to address presently or in the near future. These areas include patent policy challenge and clinical and legal challenge in nanotechnology. These two topics are closely related to the innovation process. In the case of patents, the general belief is that the "monopoly control" that a patent provides "will serve as an incentive to innovation and private sector investment".[10] Similarly, issues within the intellectual property system, as well as failures in educating "doctors & consumers" as to the advantages and uses of such technologies, have been cited as commercialization challenges.[11] There have been calls for a "national strategy to promote commercialization" here in Canada.[12] As such, both chapters illustrate good example topics of the challenge that exist as we attempt to "bridge the gap" between this novel nanotechnology situation and the current norms.[13]

Chapter 2 of this thesis illustrates that there are a variety of challenges to the patent process. The novelty of the issues and the fast evolving nature of the technology, create challenge to the patent system in Canada. Practical patent policy challenges

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[9] For instance, the National Science Foundation has granted $5 million to Center for Nanotechnology and Society at the UCSB. "National Science Foundation Selects UC Santa Barbara for New National Center for Nanotechnology in Society" *Nanotechnology Now* (6 October 2005) Online:< http://www.nanotech-now.com/news.cgi?story_id=11878> last accessed: November 16, 2005; and "NSF recently awarded Arizona State University a 5-year, $6.2 million grant under its Nanoscale Science and Engineering Program to create a Center for Nanotechnology in Society" – Center for Science and technology Policy research, University of Colorado (18 October 2005) Online:
< http://sciencepolicy.colorado.edu/extra_info.html?event_id=847> last accessed: November 16, 2005.

[10] Richard Gold, Timothy Caulfield & Peter Ray, "Gene Patents and the Standard of Care" (2002) 167 CMAJ 256-7

[11] Dr. Robert Melhalso, "Commercialization Challenges in Medical Diagnostics", (Paper presented to Euronanoforum 2005, 5 September, 2005)

[12] Arnold Naimark, "Putting life sciences to work for the health of Canadians", *The Hill Times* (16 May 2005)

[13] Ferry de Kerckhove, "Understanding public policy making processes and policy makers" Director General , International Organizations (Powerpoint presentation).

within patent offices are evident. Similarly, I consider the subject of ethical and social issues within the purview of patent law.[14] As such, questions arise regarding the use of ethical and social issues in determining the direction of patenting in this country. In analyzing this situation, I use recent Canadian patent jurisprudence to analyze a controversial, yet illustrative, example of nano patent policy challenge.

Secondly, I examine emerging ethical, legal and social issues in nanomedicine. Challenge at the intersection of health law and patent policy in nano-enabled genetic testing makes the field of nanomedicine of specific interest. Similarly, I discuss specific cases of clinical challenge in the context of lab-on-a chip technologies. In particular, the case of lab-on-a-chip technologies utilized inside the clinic in a traditional physician-patient relationship is examined. Challenges in this context include the areas of informed consent and confidentiality.

## 2. Canadian Landscape

Though the Canadian government has not released any specific legislative or regulatory measures in the area of nanotechnology, some other countries have already taken active steps in this area. For example, the U.S. has passed a piece of legislation dealing with nanotechnology.[15] In Canada, a collaborative nanotechnology, ethical,

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[14] E. Richard Gold, "Making Room – Reintegrating Basic Research, Health Policy, and Ethics into Patent Law", in Timothy A. Caulfield & Bryn Williams Jones, eds. , *The Commercialization of Genetic Research – Ethical, Legal & Policy Issues,* (New York: Kluwer Academic/Plenum Publishers, 1999) at 65

[15] The *21st Century Nanotechnology Research & Development Act* was passed in 2003. - *21st Nanotechnology Research & Development Act,* s.189, 108th Cong.(2003) – As George Allen describes "This legislation provides an organized, coordinated, and responsible approach to nanotechnology research and development (R&D) across the entire federal government. It will catalyze the synergistic interdisciplinary science and engineering research through grants to individual scientists and interdisciplinary teams of investigators. Moreover, this new law establishes a network of advanced technology facilities and collaborative research centers designed to accelerate nanotechnology R&D in

environmental, economic, legal and social issues group (NE3LS Group) as well as an "expert panel on nanotechnology" has formed. An official nanotechnology working group has been created within the Federal Department of Health.[16] Presentations and documents out of Health & Environment Canada suggest that the Government of Canada will work within the existing regulatory framework and may adapt existing strategies such as stewardship approach used in Canadian Biotechnology Strategy.[17] Sheremeta identified a wide variety of problem areas in Canada that may prove to be of interest from a regulatory perspective.[18] These include the (i) interaction of Health Canada & Environment Canada in regulation and safety; (ii) questions surrounding informed consent; (iii) privacy laws; and (iv) gene patenting.[19] Yu identified various pieces of legislation and regulations in potential need of modification in addressing some of the foregoing issues.[20] Other regulatory issues that are legitimate and

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our colleges and universities as well as in the private sector. In addition, the legislation requires the federal government to coordinate the budget requests of each of the various agencies involved in nanotechnology R&D." – George Allen, "The Economic Promise of Science and Technology" Issues in Science and Technology Online (Summer 2005) Online : <http://www.issues.org/issues/21.4/allen.html>

[16] Health Canada, Communications "Nanotechnology at Health Canada" (13 September 2004).

[17] Paul Glover, "Implications of Nanotechnology: Approaches from the Canadian Government" (Powerpoint Presentation by Paul Glover of Health Canada, May 2004) online: <http://www.iom.edu/file.asp?id=20533> ; Stephane Bergeron & Eric Archambault, "Canadian Stewardship Practices for Environmental Technology (Science Metrix: Montreal, 2005); Hans Yu ,Office of Biotechnology and Science - Health Canada "Nanotechnology Stewardship and the Management of Health Risks: Regulatory Oversight and Challenges" (Presentation to the Montreal Nanoforum, June 15, 2005)

[18] L.Sheremeta, "Nanotechnology and the Ethical Conduct of Research Involving Human Subjects"(2004) 12 Health Law Review 47 at 52-53.

[19] ***Ibid.*** at 53.

[20] Yu, ***supra*** note 17 - *Canadian Environmental Protection Act,* 1999, c.33; *Food & Drugs Act*, R.S.C., 1985, c. F-27; *Hazardous Products Act,* R.S.C. 1985, c.H-3 ;*New Substances Notification Regulations,* S.O.R./94-260; *Food & Drugs Regulations, Cosmetics Regulations, Controlled Products Regulations, Consumer Chemicals and Containers Regulations*. Given the nature of legislative/regulatory concerns, the proposed Canada Health Protection Act is noteworthy (Health Canada, A Proposal to Renew Federal Health Protection Legislation, Online:http://www2.itssti.hc-sc.gc.ca/HPCB/Policy/LegislativeRenewal.nsf/EnglishAll/ED5B120DED25284B85256D3B006FFD76?OpenDocument&L=E&>). The proposed legislation has the potential to cover regulatory gaps that occur as a result of the fast evolving nature of technology. The part of this act that is of particular interest in the area of nanotechnology is the General Safety Requirement. It will be interesting to pursue Environmental

noteworthy are those regarding the establishment of international regulatory frameworks/standards given the global significance of these issues.[21] As is stated in the literature, "it is essential to have an internationally valid standardisation of nanotechnological substances and materials as well as a uniform nomenclature".[22] This paper gives an overview of some current and future areas of nanotechnology policy challenge in Canada. The area is new, and academic discussions are largely speculative. Nevertheless, one can draw on past experience with other technologies in Canada and abroad. It is also important to proactively hypothesize about the future, using the tools we have today. As such, nanotechnology has given cause for hopes of superb innovation and advancement, particularly in the world of medicine. However, we have yet to see the full breadth, depth and width of its effects, causing speculation about numerous issues including the societal, legal and ethical affects on our population. To set the stage and introduce the complex area of nanotechnology, I discuss some general scientific definitions.

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Policy research in determining what exactly the General Safety requirement will cover and whether particular nanomaterials will be included because of the uncertainty and potential risks surrounding these products.

[21] Timothy Caulfield, "Gene Patents, Human Clones, and Biotechnology Policy: The challenges Created by Globalization"(2003) 41 ALR 713-724.

[22] Annabelle Hett, *Nanotechnology, Small Matter, many unknowns* (Swiss Reinsurance Company, Risk Perception Document, 2004) at 37; Essential to the nanotechnology regulation discussion is the subject of standardisation. In Canada, the Canada Standards Council is involved in the development and application of standards. Standards Council of Canada, Online: Standards Council of Canada http://www.scc.ca/en/index.shtml; They also work with the International Organization (ISO). ISO standards are voluntary. - International Organization for Standardization, Online: International organization for Standardization, http://www.iso.org/iso/en/aboutiso/introduction/index.html; There cannot be effective comparisons between countries of risk assessments unless there is some uniform categorization. It is interesting to note that "despite early warnings about the effects of asbestos on health, it took some 100 years to introduce internationally accepted asbestos standards." - Annabelle Hett, *Nanotechnology, Small Matter, many unknowns* (Swiss Reinsurance Company, Risk Perception Document, 2004) at 41; In the United States a Nanotechnology Standards Panel has been formed for the "development of standards in the area of nanotechnology". - ANSI, News Article, "ANSI Establishes Nanotechnology Standards Panel" (5August2004).online:AmericanNationalStandardsInstitute,Online:<http:www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=735;

## 3. Scientific Definitions

In order to better understand the matters discussed throughout this paper it is necessary to have some understanding of the terms that will be used throughout. "Nanoscience" has been defined in a number of ways including the "study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales".[23] One use of the word "nanotechnology" includes a "number of applications and products which contain unimaginably small particles and demonstrate special properties as a result".[24] More generally, the term "nanotechnology" can be described as visualizing, characterizing, producing and manipulating particles smaller than 100 nm.[25] One nanometer is 100,000 times smaller than the diameter of a single human hair.[26] A more active definition is that the technology is "focused on creation of functional materials, devices and systems through the control of matter on the nanometer scale, and the exploitation of novel phenomena and properties at that length scale."[27]Simply stated, nanotechnology is technology at the nanoscale. Nano comes from the Greek word "nanos", meaning dwarf.[28] It means one billionth of a meter. Nanotechnology distinguishes between nanostructures in materials and nanoparticles (which can be freely moving or bound in a matrix).[29] Nanostructures can be "nanosized in just 1

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[23] The Royal Society and The Royal Academy of Engineering, "Nanoscience and Nanotechnologies: Opportunities and Uncertainties" (July 2004)
[24]Hett, ***supra*** note 22 at 5.
[25]Hett, ***supra*** note 22 at 11.
[26]Kristen Kulinowski, "Nanotechnology: From Wow to Yuck?"(2004) 24 Bulletin of Science Technology & Society 13.
[27] Anisa Mnyusiwalla, Abdallah S. Daar, & Peter A. Singer, "Mind the Gap: Science and Ethics in Nanotechnology"(2003) 14 Nanotechnology R9
[28] Hett, ***Supra*** note 22 at 5.
[29] European Commission, *Nanotechnologies: A Preliminary Risk Analysis on the Basis of a Workshop organized in Brussels on 1-2 March 2004 by the Health and Consumer Protection Directorate General of*

dimension (surfaces) or in 2 dimensions (nanotubes) or in 3 dimensions (nanoparticles)".[30] A nanomaterial can be made partly or exclusively of nanoparticles.[31]. Another notable differentiation is that of molecular manufacturing and its replacement of top down manufacturing. This has been labeled a paradigm shift, the "shift from top-down to bottom-up manufacturing techniques".[32] Another distinction that is frequently made is between "near term technology" like nanoparticles and "advanced technology" otherwise known as molecular nanotechnology.[33]

Following from this brief scientific summary, the first chapter considers patent policy challenge. It is important to be mindful of the aforementioned basic definitions as I attempt to put into context, the novel nature of challenge to existing frameworks. As such, the pressing issues at patent offices, as well as the inconsistencies in patent jurisprudence warrant attention in this preemptive discussion.

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*the European Commission,* (European Communities, 2004) at 33. online:<http://europa.eu.int/comm/health/ph_risk/events_risk_en.htm.

[30] ***Ibid*** at 33.

[31]Hett, ***Supra*** note 22 at 11; There are inorganic and organic nanomaterials. Some types of inorganic nanomaterials are fullerenes and carbon nanotubes, nanowires, semi-conductor nanocrystals, and nanoparticles. As for organic nanomaterials, there has been research using DNA, Proteins, Viruses and Polymers - John C. Miller, *The Handbook of Nanotechnology Business, Policy, and Intellectual Property Law,* (Hoboken,New Jersey:John Wiley & Sons, Inc.) at 17 – 19.

[32]***Supra*** note 1 at 40; According to Hett, The categorization of nanotechnology into the top-down or the bottom up approach is described as follows:

"top down refers to processes in which a given bulk material is reduced in size to produce nanometer-scale particles, which are then either systematically inserted into larger structures or used as an admixture to other materials.....in the bottom up approach, larger structures are built up atom-by-atom or molecule by molecule, or are allowed to grow through self –assembly." - Hett, ***supra*** note 22 at 9.

[33]***Supra*** note 3 at 71.

# Chapter 2 - Patent Policy Challenge

## 1. Introduction

This chapter illustrates a smattering of novel patent issues created by nanotechnology. With the growing focus on issues related to Canadian innovation policy, such a study is a timely and relevant addition. These challenges are similar in nature to those experienced with genetics and stem cell research.[34] As such, these new technologies give support to campaigns for some revisions to patent policy. Illustratively, there have been admissions from the European and U.S. patent offices that they do not fully understand nanotechnology.[35] This would lead us to believe that the Canadian Intellectual Property Office (CIPO) probably has had or will have similar practical problems.

In addressing these difficulties, the following chapter examines several of the policy issues associated with nanotechnology and patents. In giving an overview of policy concerns, I cover a number of practical patent issues relevant to the patenting process. The unique difficulties presented illustrate the potential for new guidelines at the CIPO. In the second half of the chapter, I evaluate a specific example of a social and ethical challenge in concert with recent patent jurisprudence. This serves as a prime example of the difficulties and inconsistencies present in the patent system. These challenges are interesting and worthy of note. A general overview of the situation is necessary as the discussion begins.

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[34] Timothy Caulfield, "Nanotechnology: Facts and Fictions"(2004) 12 Health Law Review 3.

[35] Albert P. Halluin, & Lorelei P. Westin, "Nanotechnology: The Importance of Intellectual Property Rights in an Emerging Technology" ( March 2004) JPTOS 220 at 226.

Undoubtedly, there are challenges ahead for the patent system. Key questions include: How are products of molecular manufacturing to be treated within the patent system? How will the interconnected ethical, legal and social issues play out in the formation of new legislative measures, regulatory frameworks and policymaking? When one evaluates new technologies against existing patent systems, a number of patent concerns are identified. Before examining the challenges that nanotech brings to the patent system, it is necessary to note the divisions between concerns associated with nanotechnology itself and concerns associated with nanotechnology patents. Arguably, there is a distinction "between the patentability of an invention and the regulation of activity associated with an invention."[36] This position is of particular interest in the nano scenario. As I examine policy challenges in nanotechnology, it is noteworthy that clear distinctions have been made in the past between intellectual property issues and questions of health and safety.[37] On the other hand, equally strong arguments have been made for the consideration of ethical and social issues in concert with patent law.[38]For instance, it was argued in the case of human biological materials that "allocating ultimate control over these materials through a system that ignores those very concerns is likely to lead to unfortunate results".[39] Similarly, I note relevant divisions made relative to biotechnology.[40] The aforementioned divisions are mentioned in the *Harvard College v. Canada* (Commissioner of Patents)[41] dissent:

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[36] *Harvard College v. Canada* (Commissioner of Patents)[2002] 4 S.C.R. 45 at II 15
[37] *Harvard*, ***Supra*** note 36 at II 82.
[38] ***Supra*** note 14.
[39] ***Supra*** note 14 at 65.
[40] CBAC, *Biotechnology and Intellectual Property: Patenting of Higher Life Forms and Related Issues* (November 2001) at p. vi
[41] *Harvard*, ***Supra*** note 36.

> The Canadian patent system is not designed to decide about what uses of technology are permissible nor is the *Patent Act* designed to prevent dangerous or ethically questionable inventions from being made, used, sold or imported. The responsibility and tools for dealing with such matters resides elsewhere (e.g., through regulatory approval or product safety processes.[42]

In addition, this division is clear through governmental approaches like those in the *Assisted Human Reproduction Act*[43] in which some inventions are prohibited but not prevented from being patented.[44] The possibility of such changes to patent policy will be noted later in the chapter as one of the more controversial topics in nanotechnology, self-replicability, is examined in concert with predominant Canadian patent decisions such as *Harvard College v. Canada* (Commissioner of Patents)[45] and *Monsanto v. Schmeiser*[46]

Following from this, in considering policy challenge within the patent system, it is important to note some of the theoretical issues that presented in relevant technologies. For instance, in the field of genetics, commentators have suggested that "too many owners" of upstream patent rights can create "obstacles to future research."[47] Some commentators argued that this created what is known as the "anticommons" problem.[48] In this situation, knowledge needed to conduct further research is "covered by a large number of patents from different firms", and the negotiation of necessary licenses is "prohibitively high".[49] Arguably, the question of "how to maintain freedom

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[42] *Harvard*, ***Supra*** note 36 at II 65 (QL).
[43] *Assisted Human Reproduction Act* S.C. 2004, c.2
[44] *Harvard*, ***Supra*** note 36 at II 15 (QL).
[45] *Harvard*, ***Supra*** note 36.
[46] *Monsanto v. Schmeiser* [2004] S.C.C. 34
[47] Michael A. Heller & Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science at 698.
[48] ***Ibid.***
[49] Nikolaus Thumm, "Blocking Patents and their Effects on Scientific Research: Evidence from the Biotechnology Industry"(September October 2005) IP & RTD Articles at 2. Online:<ipr-helpdesk.org/newsletter/23/pdf/EN/N23_EN.pdf>

of operation for a large number of innovators, while rewarding innovation with patent rights" is a legitimate issue.[50] Similarly, Shapiro pointed out the relevant issue of "patent thickets", and resultant challenges to commercialization that are created by a "web of overlapping intellectual property rights".[51] Notably, Kieff challenged the anticommons theory using the rationale of "individual incentives".[52] Discussion of Kieff's opinion indicated that:

> Rational patent holders should always encourage others to research with their technologies…so as to increase the number of applications for their inventions and hence their own profits.[53]

More recently, Walsh et. al. conducted empirical studies into the potential difficulties created by the patent system in biomedical fields.[54] This research indicated that though the "anticommons" may be "theoretically possible, to date it has not actually occurred." [55] As well, the research of Walsh et. al indicated that "university and industrial researchers have adopted 'working solutions' that allow their research to proceed".[56] Thus, given the past difficulties iterated, one must evaluate the new situation surrounding nano inventions. The following section points out the novel practical difficulties that may occur in the actual granting of a patent. Following from this, I discuss the novel social policy issues created by self replicating inventions.

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[50] Wei Zhou, "Ethics of nanobiotechnology at the frontline" (2003) 19.2 Santa Clara Computer and High Technology Journal 481at 487.
[51] ***Supra*** note 49 at 2 ; C. Shapiro, "Navigating the Patent Thicket. Innovation Policy and the Economy"(2001) Online: <faculty.haas.berkely.edu>
[52] John R Thomas, "Scientific Research and the Experimental Use Privilege in Patent Law" (CRS Report for Congress) (28 October, 2004) at 14.
[53] ***Ibid.*** at 14; F Scott Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A response to Rai and Eisenberg"(2001) 95 Northwestern Law Review 691
[54] John P. Walsh, Ahsish Arora, & Wesley M Cohen, "Research Tool Patenting and Licensing and Biomedical Innovation" Paper presented at the OECD Conference on IPR, Innovation and Economic Performance, Paris, August, 2003.
[55] ***Supra*** note 52 at 15.
[56] John P. Walsh, Ahsish Arora, & Wesley M Cohen, "Working Through the Patent Problem" (2003) 299 Science 1021.

Concomitantly, I note potential avenues to allow a balance of the strong property rights of the inventor with equally strong social policy concerns.

## 2. Practical Patent Policy Issues

Generally speaking, every invention must be new, non-obvious and useful in order to be patentable in Canada. An invention in Canada can be defined as "any new and useful art, process, machine, manufacture or composition of matter" as well as any improvement.[57] The main reasoning behind a patent is the granting of "a statutory monopoly which is given in exchange for a full and complete disclosure by the patentee of his or her invention."[58] Given these basic tenets, one must consider the difficulties created when novel challenges are presented.

In evaluating the challenges that the patent system will encounter it is necessary to note the practical issues associated with getting a patent. To date there are no special measures at the CIPO with respect to nanotechnology.[59] It appears that Canada, United States and Europe have recognized nanotechnology as technically patentable.[60] There are a wide variety of inventions that could potentially be labeled as nanotechnology. The difficulties associated with nanotechnologies' broad definition were noted by

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[57] Roger T.Hughes & John.H.Woodley, *Hughes & Woodley on Patents* (Toronto:Butterworths,1984) at 325

[58] ***Ibid.*** at 315-2.

[59] CIPO Information Officer, Carole Choiniere (14 October, 2005) - Online General Enquiry or Publication Request Online: http://napoleon.ic.gc.ca/cipo/internet.nsf/englishcall?openform

[60] This will likely avoid the similar onslaught of patent applications that resulted when biotechnology and business method patents became patentable subject matter after substantial delay.- Timothy M. Heish, Jonathan.A. Hack, & Lawrence .F. Galvin, "The Patent Office Grapples with Nanotechnology" *Smalltimes* Online:http://www.smalltimes.com/document_display.cfm?document_id=6374 Last accessed: July 29, 2005; It appears that the United States and Europe are working within existing Patent frameworks in dealing with nanotechnology patenting. Nanotechnology Patents in the United States are covered in 35 U.S.C; Patenting of nanotechnology in Europe is covered by Article 52 of the European Patent Convention - Dagg, Nicola "The European Perspective and Regulatory Concerns of the Nanotechnology Movement" (Paper presented to the Spring 2004 AIPLA meeting) at 2

Bawa, who said, that nanotechnology "may represent a cluster of technologies, each of which may have different characteristics and applications".[61] In this section, I examine the practical patent issues that may emerge in the patenting of such inventions. It is likely that nanotechnology patent procedures and subsequent patent litigation will challenge the adequacy of present legislative frameworks. For the purposes of this paper, I examine several emerging issues, in order to present possibilities for constructive policy change. Policy reform should aid in limiting or avoiding the challenges that are mentioned below.

(i) Prior Art

A pressing issue that warrants examination in the nanotechnology era is that of prior art. The finite nature of the nanotechnology, as well as the inherent subtleties associated with such inventions present numerous complications. CIPO's current definition of prior art is as follows:

> The body of existing patents or patent applications, or any other publication throughout the world, relevant to an application or a patent.[62]

Novelty and non-obviousness standards are of particular interest when one considers issues of prior art. Noteworthy, is that the U.S. and Canada require a valid patent to be novel and non-obvious over the prior art. Unlike the U.S., in Canada there is no obligation to "disclose voluntarily all known material prior art to the Canadian Patent Office."[63]Alternatively, the applicant must respond to requests of the Canadian Patent

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[61] Raj Bawa, et. al, "Protecting new ideas and inventions in nanomedicine with patents (2005) 1 Nanomedicine, Nanotechnology, Biology and Medicine 150 at 151.
[62] CIPO Glossary, Online: http://strategis.ic.gc.ca/sc_mrksv/cipo/toolkit/gl_p-e.html
[63] Smart & Biggar, "A comparison of Canadian & U.S. Patent Systems" (28 February 2002) online:Smart & Biggar< http://www.smart-biggar.ca/Publications/index.cfm?ThisID=Articles> Last accessed: July 29, 2005

Office to "identify specified categories of prior art". [64] Given that the identification of prior art is an essential element of the patent process, one must then understand why this identification will be troublesome. Challenges associated with obtaining nanotechnology prior art have been noted by Heish et. al:

> Difficulties in obtaining nanotechnology patents will be about prior art. In some cases nanotechnology inventions are for smaller versions of an existing invention and applicants might be forced to argue that smaller is patentable.[65]

As such, it is important to pinpoint problems relevant to prior art identification in nanotechnology. For instance, literature regarding "rapidly emerging industries," notes that nano - prior art includes a "myriad of poorly indexed sources".[66] Another difficulty with identifying prior art is that many "patents are written 'not to be found'" and some [nanomedicine patents] may not use the "nanomedicine related terminology".[67] Dagg pointed out a number of problems connected with nanotechnology and prior art databases, including potential difficulties as there is a "lack or relative immaturity of nanotechnology only databases", as well as a lack of "clarity" regarding nanotech. [68] One author suggested that these problems will lead to mistakes and omissions as to what does or does not qualify as nanotechnology.[69] As a result it is difficult to identify and categorize prior art in an area that is multidisciplinary and wide ranging.

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[64] ***Ibid.***
[65] Heish, ***supra*** note 60.
[66] George Goodall, "Learning form the PTO: CIPO's solution to prior art", (March 11, 2003), Online: <www.deregulo.com/facetation/ pdfs/goodall_670_problemStatement.pdf> *Last accessed: Jan 2006
[67] ***Supra*** note 61 at 157.
[68] Dagg, ***Supra*** note 60 at 2.
[69] Dagg, ***Supra*** note 60 at 2.

CIPO does not utilize any special measures in dealing with prior art in nanotechnology.[70] The current prior art search strategy in Canada consists of an extensive international search in order to determine novelty.[71] The following ideas may generate interesting policy suggestions in Canada. The U.S. patent office recently created a "cross reference digest designed to improve the ability to search and improve the ability to search and examine nano-tech related patents".[72] The development of a "centralized nanotechnology prior art database" is another suggestion.[73] This consideration is legitimate given the multidisciplinary nature of the applications. In evaluating the expanded prior art resources for nanotechnology, other U.S. suggestions included the creation of something similar to proposals for business method patents.[74] This business method patent plan included "second review" of applications by experienced examiners and "expanded prior art collections".[75]

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[70] CIPO Information Officer, Chartrand.Odette (September 30, 2004); Carole Choiniere (14 October, 2005) - Online General Enquiry or Publication Request Online: <http://napoleon.ic.gc.ca/cipo/internet.nsf/englishcall?openform>

[71] CIPO Information Officer Guillaume Poisson (Nov 19, 2004) - Online General Enquiry or Publication Request Online: <http://napoleon.ic.gc.ca/cipo/internet.nsf/englishcall?openform>

[72] Smalltimes, "US patent office creates nano-cross reference digest" *Smalltimes* (19 Oct 2004) online:Smalltimes < http://www.smalltimes.com/document_display.cfm?section_id=53&document_id=8378> Last accessed: January 2006

[73] ***Supra*** note 35 at 231.

[74] ***Supra*** note 35 at 228.

[75] ***Supra*** note 35 at 228.

(ii) Examiners

Issues over the quality of searches lead to more substantial questions regarding the knowledge and expertise levels of the patent examiners.[76] There are concerns that patent examiners may not have the expertise to deal with this complex field.[77] A lack of examiner expertise could result in "improper rejection of patents" and patents that are "overly broad".[78] Similarly, it has been argued in Europe that this lack of expertise on the part of examiners could lead to opening of the patent flood-gates preventing or slowing attempts at follow-on-innovation.[79] Past experiences in genetics are noted when evaluating the problems of granting broad patents in nanotechnology.[80]

Consideration may have to be given to special recruitment procedures for individuals who examine patents that contain nanocomponents or incorporate nanoscience. Of course, how one would qualify as a nanotechnology expert is an issue. Currently, in Canada, patent examiners are divided into the three following categories: Chemical/Biotechnology, Electrical/Physics and Mechanical.[81] Patents typically fall under one of these categories with examiners having the relevant expertise. However, it would most likely take an individual with a very wide-ranging background to qualify as a nanotechnology expert. Given the specificity and intricacy of the area, there may need to be incentives in order to attract expert personnel into the job. Further ideas can be

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[76] ***Supra*** note 35 at 232.
[77] ***Supra*** note 35 at 226.
[78] Behfar Bastani & Dennis Fernandez, *Intellectual Property Rights in nanotechnology* (Fernandez & Associates, LLP) at 2 Online: Fernandez & Associates LLP at 5. Online: http://www.iploft.com/Nanotechnology.pdf Last Accessed: January, 2006
[79] Dagg, ***Supra*** note 60 at 6.
[80] ***Supra*** note 23 at 53 ll 11.
[81] CIPO Information Officer Guillaume Poisson (Nov 15, 2004); Pascale Gauthier(4 Nov, 2005) - Online General Enquiry or Publication Request Online: <http://napoleon.ic.gc.ca/cipo/internet.nsf/englishcall?openform>

garnered from other jurisdictions. Relevant U.S. suggestions include having a team of examiners versus one examiner, and the creation of a "centralized command centre for nanotechnology" rather than multiple isolated centers.[82] It is clear that suggestions for multidisciplinary teams are quite feasible and likely more of an organizational/management question.

(iii) Classification

Classifying nanotechnology is a pressing concern. Problems associated with classification include the blurring of boundaries between disciplines.[83] CIPO defines classification as follows:

> a system of categorizing patent documents into groups of the same type of technology. Used to assist in searching patents. [84]

Currently, there is no specific Canadian classification for nanotechnology inventions[85]. The International Patent Classification (IPC) is used to assign classes. Canada is a contracting member of the Strausborg Agreement[86] of 1971 regarding international patent classification.[87]The IPC system "promulgated by WIPO" designates

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[82] ***Supra*** note 35 at 227.

[83]According to Miller, "sophisticated nanomedical products will blur the distinction between "mechanical", "chemical", and "biological" and make it difficult to determine if a product is a drug, device, biologic, or combination product" - John Miller, "Beyond Biotechnology: FDA Regulation of Nanomedicine"(2003) 4 The Columbia Science & Technology Law Review 5 at 24. Online:<http:www.stlr.org/html/volume4/miller.pdf> Last Accessed January 2006

[84]Canadian Intellectual Property Office, Online:<http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/e-filing/gloss.htm> Last accessed: July 29, 2005

[85] CIPO, Information Officer Guillaume Poisson ( 15 Nov 2004); Online General Enquiry or Publication Request Online: <http://napoleon.ic.gc.ca/cipo/internet.nsf/englishcall?openform>

[86] This agreement "provides for a common classification for patents for invention including published patent applications, utility models and utility certificates. The International Patent Classification (IPC) is a hierarchical system in which the whole area of technology is divided into a range of sections, classes, subclasses and groups"
WIPO, International Patent Classification online: WIPO http://www.wipo.int/classifications/ipc/en/ Last Accessed: July 29, 2005

[87] WIPO, International Patent Classification online: WIPO <http://www.wipo.int/classifications/ipc/en/>

nanotechnology as "IPC class B82B".[88] The classification of B81B and B81C "micro structural technology" is also likely to be used in connection with nanotechnology inventions.[89] Until recently, there was no U.S. classification system for nanotechnology with the exception of well known area of fullerenes such as carbon nanotubes and buckyballs.[90] As a result, in most cases the patents end up being passed back and forth causing "significant delays."[91] This again relates back to the issue of expertise, and how an adequate assessment of the character of the invention can be made, by examiners who lack adequate knowledge of the field of nanotechnology. In late 2004, The Patent and Trademark Office in the United States (USPTO) set up a Class 977, "new registration category" for nanotechnology inventions.[92] This is a positive step since a clearly classified product will be processed more efficiently and accurately. Likewise, it is advantageous from an organizational standpoint, as appropriate experts will be assigned to appropriate subject matter.

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[88] LD Reich, "Protecting Tiny Gizmos", 26 *The National Law Journal* (26 Jan 2004)

[89] Dagg, ***Supra*** note 60 at 2.

[90] Stephen B. Maebius "Patent Conflicts ahead in Nanotech says Patent Lawyer" *IEEE Spectrum Online* at 2 Online:< http://www.spectrum.ieee.org/WEBONLY/wonews/jun04/0604nanqa.html> Last accessed: July 29, 2005

[91] ***Ibid.***

[92] Barnaby J. Feder, "Nanotech's Tiny Ideas Coming of Age", *New York Times* (24 October 2004) Online: ZDNet <http://news.zdnet.com/2100-9596_22-5425075.html Last accessed: July 29, 2005;(There is no US to IPC concordance for class 977 this only occurs for utility classes) US Patent & Trademark Office Online: USPTO http://www.uspto.gov/go/classification/; last accessed: July 29, 2005;Japan has classification structure with a specific category for Nanotechnology known as, "micro-structural technology; nanotechnology" - Reich, ***supra*** note 88 at 5; Class 977 description is as follows, "Nanotechnology research and development includes manipulation, processing, and fabrication under control of the nanoscale structures and their integration into larger material components, systems and architectures. Within these larger scale assemblies, the control and construction of their structures and components remains at the nanometer scale"- US Patent & Trademark Office Online: USPTO <http://www.uspto.gov/go/classification/uspc977/defs977.htm , Last accessed: July 29, 2005;

(iv) Non- obviousness Standard

The novel nano difficulties with the current non-obviousness standards may warrant new CIPO Guidelines. Arguably, the question of obviousness is a unique issue in the patenting of nanotechnology. The reason for this is the unique nature of the changes in a product from the micro to the nano level and relevant arguments over the prior art and the methods. For example, it is argued that, if when the "invention was made, methods for reducing the size of components to the nanoscale level were not known or obvious to one of ordinary skill in the art, the nanotechnology invention may be patentable".[93] A practice tip from a Canadian lawyer indicated that in attempts to patent such subject matter, one should focus on the "process or solution".[94] On the other hand, some case law in the United States "suggests that a 'mere difference in size' would not be sufficient to distinguish a nano-sized device from a conventionally sized analogue".[95] One should note that reducing the size of a known product is often deemed obvious unless "contrary to a prejudice in the art..[there is] a surprising benefit due to scale"[96]

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[93] Charles Vorndran, "The Many Faces of Nanotechnology", (2004) Intellectual Property & Technology Law 6 at 7.

[94] Lisa K. Abe, Nanotechnology:The Legal Issues (Presentation to Nanoforum Canada, 15 June, 2005) Online:www.fasken.com; Abe indicates that a "solution to a new problem arising on the nanoscale may be claimed as the invention"; Among other practice tips she indicates that focusing on the difference in environments may be helpful when the invention illustrates a "new use for a known composition in a particular environment".

[95] Sonia E. Miller, "A Matter of Scale – Nanotechnology's Novelty Poses Challenges to Patent Process", New York Law Journal, August 3, 2004

[96] Dr. Alistair Hindle "Patent Issues concerning healthcare application of nanotechnology" (Presented at Euronanoforum, 5 September, 2005)

One particular example given in support of allowing patentability based on change in size is the semiconductor industry[97]. The semiconductor industry provides an argument for the patentability of a scaled down product that implements substantial differences aside from the changes in properties seen in nanotech.[98] According to some U.S. writings, "pure miniaturizations are obvious in light of prior art".[99] However, it is undetermined whether the "different laws of physics" present at the nano-level will create differences to this line of thinking.[100] For instance, there are arguments that miniaturization creates a patentable invention because of the "quantum mechanical effects at the nanoscale".[101] This potentially creates new properties versus classic physics at larger measurements.[102] Nanotechnology can be distinguished by the property changes that occur upon a size change (for instance from the micro to the nano level). Sheremeta noted the production of unique characteristics :

> Within the nano domain, fundamental characteristics of materials that we typically presume immutable – including electrical conductivity, colour, strength, and melting point can all change. By understanding the altered characteristics of materials at the nanoscale and by tailoring the structure of materials in specific ways it is possible to engineer novel materials with characteristics that are unanticipated from macro-scale observation and measurement.[103]

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[97] Heish, ***supra*** note 60. – According Heish et.al., "In the semiconductor industry, for example, applicants have patented transistors, and they continue to patent scaled-down transistors. New technical problems arise when physical dimensions are reduced, and these new problems call for new solutions. Indeed, case law currently exists supporting the proposition that where different concepts, purposes, or objects are involved, a change in size can result in patentable subject matter."

[98] Miller notes, "While taking an existing technology and making it smaller may not result in a patent, the ability to manipulate atoms in a certain configuration creating properties with other characteristics is a patentable invention" – Miller, ***Supra*** note 95; Also worth noting is Gillard who points out that "In specifying the size of the component in numerical terms, it is important to avoid any overlap in numerical ranges with prior art components" - Richard Gillard, "Patenting in the Field of Nanotechnology", *Azonano,* Online: <http://www.azonano.com/details.asp?ArticleID=1055>, Last accessed: July 29, 2005

[99] Andrew Wasson, "Protecting the Next Small Thing: Nanotechnology and the Reverse Doctrine of Equivalents."(2004)10 Duke Law & Technology Review at II 4

[100] ***Ibid.*** at II 4.

[101] Dagg, ***Supra*** note 60 at 4.

[102] Dagg, ***Supra*** note 60 at 4.

[103] ***Supra*** note 18 at 48.

One author advised that by noting that the "improved properties" are "not shared by the known sized material" or that the methods "were not obvious", chances for patentability are increased.[104] Thus, another question that may warrant investigation is the concept of "improvement" within the Canadian *Patent Act.*[105] It is possible that arguments regarding patentability of such inventions may be made using this section of the Act. This may warrant potential reconsideration of the statutory definition of invention.

## 3. Patentability – Ethical & Social Issues contributing to Policy Challenge

Can new technologies drive the campaign for an integration of ethical and social issues in the patenting process? Strong arguments are seen on both sides of this issue and major jurisdictions have distinctively different policies on the subject. For example, there are different modes of patent policy in jurisdictions such as the U.S. which grants the patent based on traditional criteria versus some EU states that "preclude patentability" as a result of ethical and moral "challenges".[106] I focus on the issue of inclusion of ethical and social issues, and the resultant effects on innovation, in lieu of a more general discussion of ethics and nanotechnology.[107]

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[104] Jeremy M. Stipkala, "Overcoming obviousness when patenting nanotechnology inventions" (2005) 23 Nature Biotechnology 677 at 678.

[105] S.32 "Any person who has invented any improvement on any patented invention may obtain a patent for the improvement, but he does not thereby obtain the right of making, vending or using the original invention, nor does the patent for the original invention confer the right of making, vending or using the patented improvement." R.S., c. P-4, s. 34

[106] Michael J. Malinowski & Nick Littlefield, "Transformation of a Research Platform into Commercial Products", in Timothy A. Caulfield & Bryn Williams Jones, eds. , *The Commercialization of Genetic Research – Ethical, Legal & Policy Issues,* (New York: Kluwer Academic/Plenum Publishers, 1999) at 35.

[107] Notably, the ethics of nanotechnology is sometimes referred to as "nanoethics". James Moor & John Weckert, "Nanoethics: Assessing the Nanoscale From an Ethical Point of View" at 304. Online:

Among the predominant issues that have been identified in the ethical and social discourse are issues relating to nanotechnology's effects on human health, the environment, privacy and security.[108] Since scholars noted the lack of discussion on such issues related to nanotechnology,[109] a productive discourse is necessary in order to allow interdisciplinary thinkers to evaluate the issues. Hence, policymakers should aim for the subsequent production of constructive policies that "eliminate or at least minimize its [nanotechnologies] damaging effects on society".[110]

More specifically, there are numerous challenges to the patenting process, as we must accommodate nano novelties within a framework created long before such issues were relevant. A continuing debate is the placement of ethical and social issues within the patenting process. Equally problematic is that entirely new nano frameworks are likely inefficient and problematic at this stage of progress. Unfortunately, this does not alleviate the burden on lawmakers, reinforcing the need for a continuing discourse into the issues. This discourse is necessary due to the quickly changing landscape.

This section, for the purposes of illustration, considers a controversial ethical and social issue that nanotechnology brings forth for policy consideration. The case of the self replicator serves as a good example of technology that may raise ethical and social issues in patenting. Through this example, one can see the potential for inconsistencies when current patent law is applied. When evaluating self replication in

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http://www.ifs.tu-darmstadt.de/phil/Moor.pdf Some argue that we should not simply reframe "usual ethical debates". For example, reinforcing the need not to create entirely new frameworks of thought such as those of "nano-integrity or nano-autonomy". Anders Sandberg, "Smurfy Nanoethics", (2004) Eudoxa Online: http://www.eudoxa.se/content/archives/2004/10/smurfy_nanoethi.html Last Accessed: January, 2006

[108] Kim Christiansen et al., Background Paper on environmental and risk aspects of nanotechnology (2004)at 14 online: http://teknologiskfremsyn.dk/download/58.pdf Last accessed: July 29, 2005

[109] ***Supra*** note 27 at R 10.

[110] Andrew Chen, "The Ethics of Nanotechnology" (2002) Online:< http://www.actionbioscience.org/newfrontiers/chen.html> Last accessed: January 20, 2006

concert with recent Canadian Supreme Court jurisprudence, I focus on the questions that are left unresolved, thereby creating a basis for further research and policy development. Interestingly, the case for inclusion of an ordre public type provision is made. However, in order to maintain an adequate balance of patent rights, my policy recommendations entertain the need for a research exemption .

(i) NE3LS Case Study – "Runaway Technology"

In this section, I note some of the ethical and social concerns of runaway technology with a view to improving patent policy. For the purposes of illustration, I analyze evolving Canadian patent jurisprudence in concert with existing and potential inventions. In such evaluations, one should be mindful of arguments that the exclusive nature of patents should be used "to ensure the ethical use of innovations".[111]This argument bears consideration given the potential capabilities of some of these entities and the potential for change to the current methods of evaluation.

The framework for patent examination that presently exists is not designed to address the ethical and social challenges that may emerge with self replicating technologies. Therefore, the issue of self replicating devices is a unique issue and is important to consider in this context. Because of notable arguments that question the legitimacy of such innovations, we should be mindful of calls for maintaining a moderate vision.[112] A moderate position enables informed policymaking.[113] The evaluation that follows, points out inconsistencies with respect to patentability of self

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[111] ***Supra*** note 14 at 65.
[112] Robert A, Wolkow, "The Ruse and the Reality of Nanotechnology", (2004) 12 Health Law Review 14 at 14.
[113] Caulfield, ***Supra*** note 34 at 3.

replicators. A more modest initiative to allow consideration of ethical and social issues, while preserving the rights of inventors is discussed in the conclusion.

As such, one of the unique characteristics of nanotechnology, albeit highly speculative, is the possibility of self-replication. Although the discussions of runaway technology are futuristic in nature, one must consider the implications in policy discussions, particularly in patent policy. Runaway technology has become more predominant given recent fiction such as *Prey*[114] and *Oryx and Crake*[115]. Some authors noted the potential for runaway nanobots or gray goo.[116] However, there is a general avoidance of such topics in academic circles. Because such scenarios are seen to be far-fetched, the conflicting positions of Nobel Laureate Richard Smalley and Eric Drexler warrant mention. Eric Drexler has argued for the possibility of "runaway replicators", despite the contrary arguments of the late Nobel Laureate, Richard Smalley that insisted, via a number of scientific arguments, that this would never happen.[117] While Smalley challenged Drexler's position that molecular manufacturing would never take place, Drexler insisted that its progress was being "impeded by the dangerous illusion that it is infeasible".[118] However in 2004, Drexler moved forward to throw his support behind some alternatives to self replication.[119]

In light of the foregoing, this controversial innovation serves as a good example of potential policy challenge. As such, this section describes the concept of self

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[114] Micheal Crichton, *Prey*,(New York: Harper Collins, 2002)
[115] Margaret Atwood, *Oryx & Crake*, (Doubleday, 2003)
[116] Grey Goo – "A scary concept dreamed up by Erik K Drexler whereby tiny assemblers, or molecular machines, that are capable of making copies of themselves, are let loose and proceed to replicate uncontrollably, consuming everything in their path and turning it into a grey goo." – Online: <http://www.nanoword.net/library/def/Grey_Goo.htm> Last Accessed: January 20, 2006
[117] Miller, ***Supra*** note 31 at 31.
[118] ***Supra*** note 3 at 72.
[119] Eric Drexler & Chris Phoenix, "Safe Exponential Manufacturing"(2004)15 Nanotechnology 869-872

replication and tentatively applies current patent jurisprudence to self replicating inventions. This should illustrate inconsistencies and pinpoint potential nano – patent policy challenge in Canada. For the purposes of this paper, I entertain three types of replication, including the biologically based replicator, the nano-replicator and replicators that combine nano and biotech. Notably, the term "self replication" is used in many contexts.[120]

## (ii) Different types of Replication

For the purposes of this illustration, general practical divisions are made between the biological replicator, the nano replicator and the bio nano replicator. Regardless of the argued authenticity for some of these systems, there is a potential for nano replication technology and policy consideration is warranted given the hypothetical scenarios and the biological products that are already in existence.

It is important to point out some of the predominant cited differences between the modes of replication. This allows for a clear and cogent argument regarding the patentability of the self-replicator. Research indicated numerous differences between a "programmable" system of replication that is used for "manufacturing" [ie. mechanical – nano] and a biological system of replication.[121] Drexler argued that "living systems

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[120] Some examples of self replication include "natural replicators, autotrophic replicators that "reproduce in the wild", self – reproductive systems, and self assembling systems" - Answers.com, Online: <http://www.answers.com/topic/self-replication at 2 Last accessed: July 29, 2005; One concern includes "Creating trillions of nanobots at reasonable cost will require the nanobots to make themselves. This form of self-replication solves the economic issue while introducing grave dangers. Biology used the same solution to create organisms with trillions of cells, and indeed we find that virtually all diseases derive from biology's self-replication process gone awry" - Ray Kurzweil, "The Drexler-Smalley Debate on MolecularAssembly",
Online:<http://www.iranscope.ghandchi.com/Anthology/KurzweilDrexler.htm>,Last Accessed: January 20, 2006

[121] Ralph C. Merkle, "Self-replicating systems and Low Cost Manufacturing", Online: <http:/www.zyvex.com/nanotech/selfRepNATO.html>, Last Accessed: January 20, 2006.

are evolved systems, while nanomechanical replicators would be designed" systems, the former for use in a "natural environment" and the later most likely used in an "artificial environment".[122] One argument made regarding the safety of the nanoreplicator versus the biologically based replicator included the familiarity of the "parts" and "structures" of the nanoreplicator, and the fact that subsequent relations between these parts will be "designed" and "fixed".[123]

The evolutionary capabilities of biology are illustrated in existing replicators. One can see examples of a bioreplicator in the context of genetic engineering. As such, it is argued that such replicators continuously evolve and "have a capacity for further evolution".[124]Examples of "entities that can freely replicate outside of the manufacturing process" are genetically engineered crops.[125] Saner noted that such biotech patent claims could lead to replicators that "reproduce outside of factories and without permission of the patent holder".[126]Interestingly, this is not a new patenting issue, as the escape and reproduction of self-replicating genetically engineered bacteria was identified as a concern in the case of *Diamond v Charkrabarty.* [127]

Finally, I must note the potential integration of nanotechnology and biotechnological resources.[128] There is no set definition of nanobiotechnology, but one broad explanation included that it is an "understanding and control of the nanoscale

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[122] Robert A. Freitas Jr., *Nanomedicine Volume 1 Basic Capabilities* (Austin, Texas:Landes Bioscience, 1999) at 35.
[123] ***Ibid.*** at 35.
[124] ***Supra*** note 122 at 35.
[125] Marc Saner, "Backgrounder Of Mice and Men – Regulating and Using Patents" at 6. Online: Institute On Governance http://www.iog.ca/S&TGov/dec12briefing.pdf Last Accessed: January 20, 2006
[126] ***Ibid.***
[127] *Harvard,* ***Supra*** note 36 at II 51.; *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)
[128] ETC Group noted, "As the merging of living-nano and non-living nano becomes more common, the idea of self-replicating nanomachines seems less and less like a 'futurists daydream' " - ETC Group "Green Goo: Nanobiotechnology Comes Alive" *ETC Group Communique Issue # 77,* (January/February 2003) at 5. Last Accessed: January 20, 2006.

interface between biological and non-biological entities."[129] Numerous concerns exist regarding the likelihood of a green goo scenario.[130] Arguably, the "merging of nanotechnology and biotechnology,"[131] can create the products of green goo. Examples include the "combination of synthetic devices with biology, such as the insertion of a sensor in a cell"[132] Arguments include that the combination of nonbiological attributes such as "electrical conductivity" with biological attributes like "self-assembly, self repair and adaptation" may be of great benefit.[133] Notable though, it is the creation of novel and potentially dangerous products, through combining such nanoscale attributes with the evolutionary capacity of biology.

(iii) Patentability of Self replicators & Harvard Mouse

A long awaited decision in Canada that had wide ranging effects on innovation is the case of *Harvard College v. Canada* [134] Of particular interest is the effect on the biotechnology industry in Canada, given that several other jurisdictions, including Europe, United States, Australia, Japan, and Korea had ruled higher life forms to be patentable subject matter.[135] The majority of the Supreme Court of Canada held that

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[129] Foresight in Networks of Excellence – the case of "Nano-to-life (EU – US Scientific Seminar, 13-14 May 2004, Seville ,Spain) Online: <www.ictaf.tau.ac.il/foresight_n2l.pdf> Last Accessed: January 20, 2006

[130] "Concerns include "the merger of living and non-living matter will result in hybrid organisms and products that end up behaving in unpredictable and uncontrollable ways. In a "green goo" scenario, a designer microbe turns out to have designs of its own." - J Craig Venter, "Playing God in the Galapagos" *ETC Group Communique #84* (March /April 2004) at 5. Last Accessed: January 20, 2006

[131] "New nanotech risk revealed: runaway green goo could be created by nanobiotech gone bad" Online: http://www.newstarget.com/001414.html, Last accessed: July 29, 2005

[132] ***Supra*** note 130 at 6

[133] ***Supra*** note 128 at 4.

[134] *Harvard*, ***Supra*** note 36.

[135] Konrad Sechley, "Schmeiser versus Monsanto" (2004) 22 Nature Biotechnology at 804.

higher life forms, in this case, the mouse containing the oncogene, were unpatentable subject matter.[136]

Although the characteristic of self-replicability did not factor into the end decision and, in fact, "issues peripheral to whether the mouse constituted statutory subject matter", for example "reproducibility", were "dispensed with"[137], the self-replicating issue still warrants policy consideration. Given the controversial nature of some nanotechnological developments, and that the *Patent Act* [138] has not been written to encompass these issues, constructive policy development on the matter is necessary.

First, I will discuss how self replicability was handled/ viewed in the case of *Harvard College v. Canada.* [139] As we know, higher life forms can self replicate. Binnie, J. speaking for the dissent pointed out the majority's view that a key distinguishing point in the case was "the unique ability of higher life forms to self replicate".[140] The dissent argued that this was faulted because lower life forms can also self replicate. [141] This is a valid argument as many lower life forms such as cells are in fact self replicating and in practice patentable. Arguably then, the self-replicating characteristic did not factor into the final findings.

Given the limited nature of the invention definition,[142] and the differing views as to what that encompasses, a key policy concern should be that of the self replicating characteristic. One should note relevant policy issues mentioned in the decision. Policy

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[136] *Harvard, **supra*** note 36.
[137] T. Andrew Currier, "The Impact of Harvard Mouse on The Canadian Law Pertaining to Statutory Subject Matter" 19 Canadian Intellectual Property Review 219 at 222.
[138] *Patent Act* R.S.C. 1985, c. P-4
[139] *Harvard, **supra*** note 36.
[140] *Harvard, **supra*** note 36 at II 51(QL.)
[141] *Harvard, **supra*** note 36 at II 51(QL).
[142] Invention - "any new and useful art, process, machine, manufacture or composition of matter" as well as any improvement". ***supra*** note 57 at 325.

arguments that the Canadian Biotechnology Advisory Committee covered in the *Harvard College v. Canada* (Commissioner of Patents)[143] judgment included observations that higher life forms can self-replicate that is, reproduce by themselves.[144] As a result, CBAC further argued that "the grant of a patent covers not only the particular plant, seed or animal sold, but also all of its progeny containing the patented invention".[145] The CBAC argued that this gives an unsuitable scope to patent holders' rights inconsistent with other areas.[146]As we see in the *Monsanto v. Schmeiser,*[147]decision that will be discussed hereafter, this holds true when a certain amount of control is garnered by the patent holder via such self replicating measures. Similarly, the majority in *Harvard College v. Canada (Commissioner of Patents)* in discussing the exclusion of plants from patentability suggested that reasons may include plants' "capability to self propagate" and the ensuing infringement issues this creates.[148] While replicate means to "make a copy" and "propagate" means to "multiply or breed", the argument could be made that such terms on occasion could be interchangeable.[149] It is arguable then in this context to consider self propagation/replication a detriment when aiming for patentability.[150] Given the interchangeability of the terms, the policy concerns voiced regarding plants in this context could work for any case to be made against the self replicating entity.

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[143] *Harvard*, ***supra*** note 36.
[144] *Harvard*, ***supra*** note 36 at II 170 (QL).
[145] *Harvard*, ***supra*** note 36 at II 170(QL).
[146] *Harvard*, ***supra*** note 36 at II 170 (QL).
[147] *Monsanto*, ***supra*** note 46.
[148] *Harvard*, ***supra*** note 36 at II 204.
[149] Online: < http://dictionary.reference.com/search?q=propagate>
[150] In this decision other relevant recommendations by the CBAC that are mentioned include the farmers privilege provision and the innocent bystander provision to deal with individual instances of self-replication - *Harvard* ***supra*** note 36 at II 170.

(iv) Patentability of Self – Replicators & Monsanto

Of more recent note is that *Monsanto v. Schmeiser*[151] recognized the validity of Monsanto's patent on the genetically modified genes and cells.[152] As per *Harvard College v. Canada (Commissioner of Patents)*[153], *Monsanto v. Schmeiser*[154] reiterated that plants are "included in the category of higher life forms" and therefore not included in the category of invention.[155] However, the interesting development in this case was that the patented genes and cells present throughout the plant arguably allowed the patent holder to direct control over the plant, given that "protection for the higher life form may be obtained as a result of the higher life form comprising the novel cell".[156] Thus, as we consider policy challenge in nano, recommendations such as, "making non-human higher life forms patentable with certain safeguards,"[157] are legitimate and transferable to this scenario.

Specifically, I consider the characteristic of self replicability and how it was dealt with in *Monsanto v. Schmeiser*[158]. The case for eliminating self-replicable entities from patentability has been heard before. Lower court arguments from Schmeiser included that patent protection "ought not to extend to things which are capable of self-replication and which are therefore impossible to contain or control".[159] However, the trial judge in Monsanto rejected arguments that "the gene and cell are unpatentable

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[151] *Monsanto*, ***supra*** note 46.
[152] *Monsanto*, ***supra*** note 46.
[153] *Harvard*, ***supra*** note 36.
[154] *Monsanto*, ***supra*** note 46.
[155] *Monsanto*, ***supra*** note 46 at II 112.
[156] ***Supra*** note 135 at 804.
[157] CBAC, "Rationalizing Patent Law in the Age of Biotechnology" (Canadian Biotechnology Advisory Committee, September 2004) ar 2 Online:< http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00484e.html> Last Accessed October 16, 2005
[158] Monsanto, ***Supra*** note 46.
[159] Lee M. & Burrell R., "Liability for the Escape of GM Seeds: Pursuing the Victim?" (2002)65 Modern Law Review 517 at 521. Online:< http://ssrn.com/abstract=317845 >

because they can be replicated without human intervention and control".[160] As such, the trial court does not use self replicating without human intervention as a bar to patentability.

The issue of self replicability and the relevant difficulties associated with it continued to arise in this case. Of note is that the Federal Court of Appeal cited in *Monsanto v. Schmeiser*[161], acknowledged the difficulty of placing "self replicating materials" within the "confines of the *Patent Act*"[162]:

> "...It seems to me arguable that the patented Monsanto gene falls into a novel category. It is a patented invention found within a living plant that may, without human intervention, produce progeny containing the same invention"[163]

As we see in the final decision, it is arguable that the "transgenic higher life form [plant containing patented genes and cells] may be protectable".[164] However, we also see in *Monsanto v. Schmeiser* [165] and *Harvard College v. Canada (Commissioner of Patents)*[166] a discussion of a dividing line between the product of the laws of nature and that which is a product of human intervention. It is argued that the plant cell claim in *Monsanto v. Schmeiser*[167] ended at the point when "the genetically modified cell begins to multiply and differentiate into plant tissues".[168]However, we see in the end this did not affect the plant cell claim. Similarly, a question posed in *Monsanto v. Schmeiser*[169] is whether a "patented product (the gene or cell) extends patent protection to the

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[160] *Monsanto, **supra*** note 46 at II 14.
[161] *Monsanto, **supra*** note 46.
[162] Monsanto, ***supra*** note 46 at II 154(QL)
[163] *Monsanto, **supra*** note 46 at II 154(QL).
[164] ***Supra*** note 135 at 804.
[165] *Monsanto, **supra*** note 46.
[166] *Harvard, **supra*** note 36.
[167] *Monsanto, **supra*** note 46.
[168] *Monsanto, **supra*** note 46 at II 138 (QL).
[169] *Monsanto, **supra*** note 46.

unpatentable object into which it is incorporated."[170] This again was not clearly distinguished as in the end, although the plant was not patentable, the use of the plant containing the patented product was a factor in patent infringement. Again, the question is complicated by the fact that in the case of a plant or other self replicating/propogating entity it can "subsequently grow, reproduce, and spread with no further human intervention".[171] Notably, questions about control of the self replicating final product (plant) have not been fully answered.

### (v) Applying the case law to Self Replicators

A biologically based replicator is a living entity existing in both higher and lower life forms that has evolved in most instances via the laws of nature. The nanoreplicator is a non-living entity that has been created via human intervention. A bio-nano replicator can potentially exist in both higher and lower life forms, is a combination of the living and the non-living and is a production of the laws of nature and human intervention. Thus one must conclude based on current case law there would be a split between the patentability of the self replicating higher life form and the self-replicating lower life form.

As we move forward with policy considerations, tentative conclusions can be made using these aforementioned cases. This exercise can illustrate where some of the difficulties may lie. The bioreplicator will be patentable based on whether it is a higher or a lower life form and on whether it is a transgenic entity [For example, a plant containing patented genes or cells]. In my analysis, the nanoreplicator falls within the

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[170] *Monsanto*, ***supra*** note 46 at II 156 (QL).
[171] *Monsanto*, ***supra*** note 46 at II 156 (QL).

manufacture definition of invention, consisting of statutory subject matter, in that it is a "non-living mechanistic product or process" [172] As well, it is a product of human intervention and most likely patentable.

The bionanoreplicator will incorporate features of the living and non-living and is a product created via the laws of nature and human intervention. Arguably, based on the reasoning in *Monsanto v. Schmeiser*[173] and *Harvard College v. Canada* (Commissioner of Patents)[174] this type of replicator will either be patentable or not patentable depending on its stage of development. A lower life form replicator would likely (but not necessarily) be ruled patentable over replicators that have evolved/differentiated into a higher life form. Thus the categories of self replicating entities may have to be differentiated in future with respect to the degrees of intervention and the possibilities of propagation/replication. This unique situation would create an impetus to move away from traditional categories of determination given the many ethical and social issues that are raised.

Arguably, based upon the dissent views, the bionanoreplicator that incorporates the living and the nonliving in the context of replication could be evaluated with the laws of nature objection iterated in the aforementioned *Harvard College v. Canada* (Commissioner of Patents).[175] The argument in *Harvard College v. Canada*[176] dissent specified that "an inventor whose invention harnesses the forces of nature is no less an inventor."[177] This argument is further enhanced when one considers that the argument

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[172] *Harvard, **supra*** note 36 at 159 (QL).
[173] *Monsanto, **supra*** note 46.
[174] *Harvard, **supra*** note 36.
[175] *Harvard, **supra*** note 36 at II 84(QL).
[176] *Harvard, **supra*** note 36.
[177] *Harvard, **Supra*** note 36 at II 87(QL).

that genetic subject matter, if useful, is patentable, although technically it is a product of nature.[178] Hence, it is obvious that even though one can draw numerous conclusions based on the trends in the aforementioned cases, the self replicating characteristic is arguably a feature that creates policy dilemmas. Given the trends and issues surrounding biotechnology, it is necessary to be proactive on the nanotechnology front. As is illustrated next, it is obvious that some of the ethical and social ramifications associated with such inventions warrant further investigation.

(vi)Should nanotech be "unpatentable" because of self-replicability?

In practice, lower life forms (for ex. cells) are patentable and self-replicating[179] and higher life forms (which also could potentially be self replicating) are not patentable[180]. Officially then, the case law is split on what self replicating entities are in fact patentable. The arguments presented throughout this discussion illustrate the obvious inconsistencies in patentability of such inventions. Since the issue of self replication has been discussed in Canadian patent cases in recent years, it is critical that nanotech be considered in policy discussions. In support of this are arguments that patent law was "written before self-replicating products were a reality".[181] As well, arguments exist for the patentability of the mechanistic nanobot and the difficulties that exist with patenting biologically based self replicating entities:

> Microscopic biorobots, unavoidably derived from natural biological material, may someday be deemed unpatentable under a general prohibition on "genetic colonialism" or other emerging legal doctrines. In contrast, mechanical

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[178] Institute on Biotechnology and the Human Future, Online: http://www.thehumanfuture.org/topics/genepatents/policy.html Last Accessed: July 29, 2005
[179] *Monsanto*, ***supra*** note 46.
[180] *Harvard*, ***supra*** note 36.
[181] ***Supra*** note 125 at 6.

> nanorobots, being fully-artificial and designed machines, should always be patentable provided they satisfy the customary legal criteria.[182]

This is but one position that evaluates self replicators in concert with existing legal principles. Even more complex is the case of nano-bio that brings a host of concerns including those of safety. As a result of the policy and case law arguments that have been raised, there are arguments for and against change. The debate remains whether the potential effects of such inventions warrant a distinct shift in how the grant of a patent is determined, and how the courts subsequently determine the validity of that patent. In other words, should patent legislation help to address the social issues associated with such inventions?

There are a number of policy concerns that have been raised regarding self-replication. These concerns do warrant mention in the discussion on self-replicators and patenting. There are fears that self-replicating technologies such as genetically modified (GM) plant and animals, and bioweapons could be creating new "toxins" and "pests".[183] For instance, Cullet noted the issue of biosafety as a "complementary" aspect of the Monsanto patent dispute.[184] The reasoning behind this was that "a GM construct which has the potential to self replicate" was introduced "into the environment". [185] These scenarios are enhanced by nano-applications of like technologies. Likewise, one concern is that "self- replicating nanomachines" could be utilized in warfare.[186] The

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[182] ***Supra*** note 122 at 35.
[183] Dustin R Mulvaney & Jennifer L Wells, "Biotechnology, the life science industry and the environment" Online: <www.globetrotter.berkeley.edu/EnvrPol/Bib/B09-MulvaneyWells.pdf >at 5.
[184] Philippe Cullet, "Farmer Liability and GM Contamination: The Schmeiser Judgement" Online: International Environmental Law Research Center http://www.ielrc.org/content/n0404.htm Last Accessed October 16, 2005.
[185] ***Ibid.***
[186] Brent Silby, "Nanomachines: Nanotechnology's Big Promise in a Small Package" Online:< http://www.def-logic.com/articles/nanomachines.html>

uncertainty of how newer, more finite inventions with indeterminate capacity will be handled in future is problematic. As such, clear determinations as to the patentability of such inventions should be investigated.

Another important consideration is the patentability of self replicators in the context of nanomedicine. For instance, many predictions for nanomedicine include self replicating products. It has been argued in the nanomedicine context that medical devices used inside the human body should not self replicate.[187] Nanomedicine concerns from a surgical perspective included that technology can stall, for example if you put device in how do you remove it?[188] Interestingly, some nanobot therapeutics "may be modified bacteria and viruses."[189]On the other hand the promise for medical advance is great and should not be downplayed. This being said, the patentability of such instruments will probably be among the first to be involved in litigation proceedings. One area that may come into question is the medical use exemption in the *Patent Act* [190]. A method of medical treatment is not patentable in Canada.[191] However, important to this discussion is that " 'use' claims such as those allowed in Europe are permitted in Canada."[192] It has been noted that a self replicator could be patented for its medical use,

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[187] Robert A. Freitas Jr. *Nanomedicine Volume II Biocompatibility* (Landes Bioscience, Austin, Texas: 2003) at 162.
[188] Nanotechnology-Promising a Revolution in Healthcare (5 September 2005, Euronanoforum, Edinburgh, Scotland)
[189] The Institute of Nanotechnology, UK., Otilia Saxl , *Nanotechnology – What it means for the Life Sciences.* Online: <www.nano.org.uk>
[190] *Patent Act* R.S.C. 1985, c. P-4
[191] *Tennessee Eastman Co. et al. versus Commissioner of Patents (1972), 8 C.P.R. (2d) 202*
[192] Anita Nador, "The Patenting of Biotechnology in Canada" Online: http://www.samedanltd.com/members/archives/EBR/Spring2002/AnitaNador.htm

and that "in vitro versions" may be protected when one cannot protect the actual therapeutic method. [193] This may be an avenue worth addressing in policy discussions.

Thus, in the future, it may be unavoidable to consider ethical and social arguments in concert with traditional Canadian patent schemes. As we have seen in the case of biotechnology, policy suggestions have included that Parliament should determine applicability of nanotechnology and that definitive answers should be "clearly articulated" in a "revised Patent Act".[194] However, there are credible alternatives to totally revising the *Patent Act* as will be noted below.

## (vii) Does nanotechnology warrant further discussion of "Ordre Public"?

Given the controversial nature of nanotechnology products such as self replicating technologies, a relevant policy could be introduced into the *Patent Act* [195], or as suggested in *Harvard College v. Canada (Commissioner of Patents)*[196] "put into special legislation equivalent to the ... Assisted Human Reproduction Act".[197] Of particular interest in this situation is the NAFTA and TRIPS "ordre public" provision.[198]

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[193] Workshop Two "Intellectual Property Issues Affecting Nanoscience", ( Euronanoforum,Edinburgh, Scotland, 5 September , 2005)
[194] ***Supra*** note 157 at 2.
[195] *Patent Act* R.S.C. 1985, c. P-4
[196] *Harvard,* ***supra*** note 36.
[197] *Harvard,* ***supra*** note 36 at II 93 (QL).
[198] As per *Harvard,* ***Supra*** note 36 at II 90, "NAFTA and TRIPS each provide that contracting states may exclude from patentability inventions the exploitation of which would be contrary to ordre public (which seemingly equates to the protection of public security, the physical integrity of individuals as members of society, and the protection of the environment) or morality: North American Free Trade Agreement Between the Government of Canada, the Government of the United Mexican States and the Government of the United States of America (1992), Can T.S. 1994 No. 2 (entered into force January 1, 1994), art. 1709(2); Agreement on Trade-Related Aspects of Intellectual Property Rights (April 15, 1994), 1869 U.N.T.S. 299, art. 27(2). The exclusion presupposes a general rule of patentability. Parliament has amended the Patent Act to take account of each of these agreements, but has chosen not to include such an exclusion from patentability in the Patent Act."

Even though the Canadian *Patent Act* [199] was amended to take "account" of these provisions, the Act itself has no such exclusion from patentability.[200] The *European Patent Convention* has a clause that deals with ordre public and morality.[201] The aforementioned clause, Article 53, expresses that the "self-replicating nanomachine or nanobot" may be held to be in contravention of the ordre public and therefore not patentable".[202] There are concerned calls for consideration of policies such as ordre public given the nature of some self replicating nanobiotechnological products.[203] These arguments point out the difficulties with containing the "genetically modified organisms" and speculate further as to how the products of nano-bio will be contained.[204]

The possible inclusion of such a clause into the *Patent Act* [205] would change the face of patenting in Canada. Arguments that have been made against the EPC ordre public provision include that it has served as a "back- door" by pressure groups opposed to biotechnology in order to attack activities that are "perfectly legal".[206] Important to note are suggestions that "government should encourage creation of an international body that would provide advice to nations concerning the application of ordre public" to enable an effective determination of issues.[207]

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[199] *Patent Act* R.S.C. 1985, c. P-4
[200] *Harvard, **supra*** note 36 at II 90.
[201] *Harvard, **supra*** note 36 at II 91.
[202] Dagg, ***supra*** note 60 at 3.
[203] According to Civil Society organization ETC, "nanotechnologists are busy building biological machines or hybrid machines employing both organic and inorganic matter - from the bottom-up...The implications are breathtaking: not just new species and new biodiversity - but life forms that are human-directed and self-replicating. Nanobiotechnology is moving science from genetically-modified organisms to atomically-modified organisms."- ***Supra*** note 130 at 2.
[204] Venter, ***Ibid.*** at 5.
[205] *Patent Act* R.S.C. 1985, c. P-4
[206] AIPPI, "Questionnaire May 2003 Q178 Scope of Patent Protection – Response of UK Group" Online: <www.aippi.org/reports/q178/quest03/q178-uk.pdf>
[207] Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms* (June 2002)

Another relevant suggestion that has been made by Canadian scholars in order to deal with social and ethical questions in patenting is the use of an "independent, transparent, and responsible tribunal made up of specialists in ethics, research, and economics."[208] In this scenario, inventions of questionable ethical and social character would be subject to suspension by said tribunal.[209]

The controversies and dilemmas present in biotechnology are further enhanced by nanotechnology progress. Is it possible, that as policy change is still in progress for aforementioned biotech developments, policymakers can extrapolate and adjust in order to address the new social and ethical concerns presented by nanotechnology? As always, what is actually morally and ethically reprehensible to one may not be to another. That is why a balanced approach, incorporating all viewpoints, must be utilized. As has been noted, "it is difficult to incorporate ethical implications in the decision making processes unless the decision makers are thoroughly educated about how to evaluate ethical issues".[210] In this type of evaluation it is also difficult to discern where authorities' real interests lie.

In summary it is important to note that the inclusion of an ordre public should be offset by clause that maintains the economic importance of strong property rights for inventor. These clauses could include a experimental use exemption and/or clarification of the method of medical treatment.

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[208] Richard E. Gold & Timothy Caulfield, "The Moral Tollboth: a method that makes use of the patent system to address ethical concerns in biotechnology" (2002) 359 Lancet 2268

[209] ***Ibid.***

[210] ***Supra*** note 50 at 488.

## (viii) Conclusions

Tentative conclusions on the patentability of the bioreplicator, the nanoreplicator, and the nanobioreplicator as per recent Canadian patent cases of *Harvard College v Canada (Commisioner of Patents)*[211] and *Monsanto v Schmeiser*[212] have been given. These are very preliminary discussions as the existence and usefulness of some of these entities has yet to be shown. It is useful to note the basic differences as all self-replicating entities will not be identical. Therefore different categories may warrant different policy treatment and direction. The scenarios described above serve as good examples where policy responses to the nano challenge may be required. Using these illustrations, it is useful to hypothesize what some possible alterations to patent policy might be. Following from this general patent discussion, I now shift to a nanomedical focus. Examples of clinical challenge intertwined with health and patent policy illustrate further legitimate challenges to the innovation process.

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[211] *Harvard*, ***Supra*** note 36.
[212] *Monsanto*, ***Supra*** note 46.

# Chapter 3– Nanotechnology: Unique Clinical & Legal Challenges

## 1. Introduction

Of immediate concern in the nano world is the adequacy of existing legal frameworks. For example, given the fast evolving world of genomic and proteomics aided by well funded research[213], it is essential to craft policy frameworks that can moderate the changing landscape. Nanomedicine will challenge established norms and practices in the physician patient relationship and resultantly in the clinical setting. Such issues include those of informed consent and confidentiality. In concert with these clinical concerns, are continuing policy concerns that exist at the intersection of the patent system and the public health system.

Nanotechnology (nanomedicine)[214] initiatives are facilitating the development of new tools that enable genomics and bioinformatics. The incremental shift from micro to nano is indicative of the direction of development with many of these innovations. Emerging nano-enabled technologies aim to instantaneously present multiple and comprehensive results. One important point for us to consider is what policy challenges

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[213] 2003 Federal Budget provided $75 million to develop tools of genomics and proteomics. Online: www.genomecanada.ca ; Recent awards of $16 million have been made to U of A researchers to study genomics from different angles. Iris Tse, "Genomics researchers receive funding boost" *Express News* (28 October 2005)

[214] One area of nanotechnology discussed in this paper that will produce policy challenges is nanomedicine. There are a variety of areas that will be affected including, tissue engineering, nanoscaffolds and interfaces, drug delivery and pharmaceutical development, cell structure and function, congenital and degenerative diseases, nanoimaging and functionalized nanoparticles, novel implants and devices, nanosensors and diagnostics. These subject areas were focused on at Nanotechnology and the Health of the EU citizen in 2020, September 5-9, 2005; It has been argued that through the use and the integration of nanotechnology with biotechnology and medicine, "scientists can now view and interact with basic life processes.",
Sonia E. Miller, "The convergence of N: Nanotechnology, Nanobiotechnology, and Nanomedicine" (2003) 230 New York Law Journal 2
online:<http://www.ctba.us/articles/NYLJ.ConvergenceofN.120203.pdf>

such diagnostics create in the clinical setting. New issues arise as specific chips under development for use in a clinical setting have been described as being "fast, accurate, sensitive, inexpensive, portable, Internet-enabled and easy-to-use."[215] Similar to the advances in biotechnology, these nanotech innovations may be deemed "transformative" in methods of "prevention, detection and treatment of disease and disability".[216] As well, these new forms of nanotechnology diagnostics will allow for increased sensitivity and accuracy and will likely pave the way for extraordinary advances in medical care.[217] For example, the new forms of nanotechnology diagnostics may provide early diagnosis and treatment in support of a preventative medicine approach. This could lead to decreased health care costs.[218] On the other hand such genetic tests can be viewed as expensive.[219] For instance, there have been concerns expressed in the past (eg. biotechnology) over the ability to adopt and fund technically complex and "disruptive" technologies.[220] Thus, the novel circumstances associated with such technologies will present challenge in healthcare system, including the adequate maintenance of the doctor/patient relationship. If such technologies are to succeed, policies must address the relevant concerns.

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[215] Photonics. Microsystems for Bioscience: Progress in (20 September , 2004) http://www.cmc.ca/news/events/mrdcan/highlights/highlights2004.htm

[216] Canadian Biotechnology Advisory Committee, *Biotechnology and Health Innovation: Opportunities and Challenges* (March 2004) at 6. Online:< cbac-cccb.ca/.../$FILE/ BHI_Discussion%20Paper_13May04_Final_English.pdf> Last Accessed:January 20, 2006

[217] Kenneth Chang, "Nanoparticles: Size is Everything" *Edmonton Journal* (6 March 2005) D9; Similar issues have arisen in discussion of DNA chip patent issues and the affect on research and innovation. – ***Supra*** note 14 at 65.

[218] Timothy Caulfield et. al, "Genetic Technologies, health care policy and the patent bargain" (2003) 63 Clin Genetics 15 at 16.

[219] ***Ibid.*** at 16.

[220] Canadian Biotechnology Advisory Committee , *Biotechnology and the Health Of Canadians*, (June 2005) at 12. Online: <cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/ vwapj/BHI-Brochure_e.pdf/$FILE/BHI-Brochure_e.pdf> Last Accessed: January 20, 2006

A key premise for policy change in the clinical setting is the instantaneous and comprehensive nature of the results. Particular to this discussion, are the aforementioned "lab on a chip" technologies, specifically those utilizing nanotechnology. For example, one application of nanotechnology being utilized at the University of Alberta is in the form of a chip that will eventually allow multiple tests per chip, giving instantaneous, standardized results. Valuable characteristics underlying the question of policy challenge include:

> more rapid and informed clinical decisions and personalized treatments for cancer, as well as rapid blood typing for organ transplantation and real-time genetic and protein profiling.[221]

Due to these improvements, one can hypothesize that previous challenges in the clinic will promise to continue in an amplified form. Understandably, legal and ethical issues that were already present in genetic testing are now magnified via aforementioned nano-enabled technologies. For instance, proper provision of genetic counseling,[222] genetic testing and screening, and the chances for genetic discrimination will continue to be key policy challenge areas.[223] In addressing these concerns, one must view the legal frameworks, case law, etc., currently in place relevant to genetic testing in order subsequently identify potential policy challenge areas.

Similarly, there are continuing difficulties with integrating "discussions of health policy, ethics and social values" into patent law.[224] Particular concerns include

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[221] ***Supra*** note 215.
[222] Mona Sidarous & Estelle Lamothe, "Norms and Standards of Practice in Genetic Counselling" (1995) 3 Health Law Journal 153 at II 56
[223] Bartha M. Knoppers & Ruth Chadwick, "Human Genetic research: emerging trends in ethics", 6 Nature Reviews (2005) 75 at 75.
[224] ***Supra*** note 14 at 65.

the use of these technologies in the most equitable and accessible way. This aids public acceptance through cultivating trust[225]. Because of the conflicting agenda present in patent and health reform there are many challenges ahead. As such, the effects of new nanomedical technologies will be wide ranging.

In forming a framework for consideration of these issues, this chapter gives a brief overview of the technology and some of the imminent policy challenges. The discussion of some relevant ethical issues and social effects will aid in an evaluation of how to best deal with the public's reaction to nanotechnology.[226] Throughout the discussion it becomes obvious that the pairing of nanotechnology and genetics will create notable shifts and broad consideration of present policies. There are numerous similarities between the genetics and the nanotechnology revolution as has been illustrated in recent writings.[227] There are also a number of ethical and social concerns associated with the availability of genetic information that persist in this nano scenario but are not the focus of this discussion. Thus in examining the pertinent and imminent issues relative to technology and the law, one should surmise how these scenarios may play out in future litigation. Such examinations will give strength to campaigns for productive policy change.

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[225] Innovation, Health Research and Canada's Prosperity, 20 Recommendations from a national conference: Advancing Health, Science and the Economy (October 2001, Toronto) Online:< www.merckfrosst.ca/e/health/ policy/pdf/innovativehealth_2c.pdf>

[226] ***Ibid.***

[227] Fiona Moore, "Implications of Nanotechnology Applications: Using Genetics as a Lesson" (2002) 10 Health Law Review 9.

## 2. Nanotechnology – Unique Applications in the Clinic

In order to put this discussion into context, a brief and simple explanation of the technologies characteristics is necessary. Through the "lab-on-a-chip" technology, nanotechnology has permitted "miniaturization of complex reaction processes into small, self contained packages".[228] The resultant speedy convenience and compact nature of these devices is a key element of this debate. Some of these systems utilize "nanofluidics" and "microfluidics."[229] Noteworthy, is the fact that fluid flow behaviors (in nano and micro channels) are very different in micro scale than in macro scale.[230] As well, micro and nano technologies can be used for single cell analysis.[231] For example, nanotechnology can actually allow conduction of "cell biology on a chip", by replicating the microenvironment in which the cell usually grows (via a nanofluidic chip).[232] Some of these systems produce "high resolution molecular separations" in which case many functions can be performed on a single chip.[233] On one chip there can

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[228] David Mabey, Rosanna W. Peeling, Andrew Ustianowski, & Mark D. Perkins, "Diagnostics for the Developing World"(2004) 2 Nature Reviews 231 at 238.

[229] Linda M. Pilarski et. al. , "Microsystems and Nanoscience for Biomedical Applications: A View to the Future" (2004)24 Bulletin of Science Technology & Society 40 at 41.

[230] Chong Ahn, "Microfluidics and Lab – On – A Chip", (3rd Annual MEMS Technology Seminar 19-21 May, 2003)

[231] Helene Andersson & Albert van de Berg, "Microtechnologies and Nanotechnologies for Single Cell Analysis" (2004) 15 Current Opinion in Biotechnology 44; According to the US Dept of Health & Human Services, nanotech will utilize relevant developments previously implemented at a larger scale, "A good example of this approach will capitalize on existing "lab on a chip" and microarray technologies developed at the micron scale. Widely used in biomedical research and clinical diagnostic applications today, these technologies will find new uses when shrunk to the nanoscale. There they will be able to interact with an individual cell in real time and in that cell's natural environment." - U.S., Dept of Health and Human Services, National Institutes of Health, National Cancer Institute, *Cancer Nanotechnology Plan, A Strategic Initiative To Transform Clinical Oncology and Basic Research Through the Directed Application of Nanotechnology*" (July 2004) at 25. Online:<http://www.nano.cancer.gov/alliance_cancer_nanotechnology_plan.pdf>

[232] Cancer Nanotechnology Symposium, "Nanotechnologies as Enablers of Breakthroughs in Cancer Early Detection and Therapeutics", (National Cancer Institute Symposium , March 4, 2004) at 8

[233] Linda Pilarski et. al., "Improved Diagnosis and Monitoring of Cancer Using Portable Microfluidics Platforms", (Proceedings of the 2004 International conference on MEMS, NANO, and Smart Systems) at 1

be "several functions or modules" resulting in a "high level of integration".[234] Potential benefits resulting from these characteristics include that these systems may lead to a better understanding of diseases such as multiple myeloma.[235] Similarly, some of these systems can test blood, bone marrow and other tissues in order to identify "cancer signatures".[236] As well, there are claims that such microfluidic chips "can warn of potential adverse drug effects, monitor vaccination efficiency, detect disease-related genetic abnormalities," with a touted focus on "personalized medicine". [237]

Multiplex systems can use unique "detection strategies" to achieve results at the nanoscale.[238] These systems are based on "novel nanotechnology based diagnostic tags", leading to cost benefits as they need minimal amounts of sample and take up little room.[239] Among the technical benefits are "simultaneous analysis of multiple markers on one sample", and a chance for an earlier diagnosis.[240] Despite these apparent advantages, this type of testing will create numerous problems with ensuring the physician will receive adequate consent. For example, how can counseling and consent

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[234] Christopher J. Backhouse et al., "Use of Microchip Modules to Analyze Myeloma" Online:< http://www.cancereducation.com/CancerSysPagesNB/ abstracts/mmrf/7/aaqu6.pdf ; "Microfluidic Devices Using Principles of Integration", Online:<http://www.azonano.com/details.asp?ArticleID=426>

[235] ***Ibid.*** at 1.

[236] ***Supra*** note 233 at 3; A recent news article notes Pilarski's impressions of affects on healthcare, "Imagine a Canada where complex medical test results are available almost instantly, where aging Canadians can perform home-based testing with almost instantaneous transmission to a doctor's office, where emerging or relapsing cancer can be rapidly detected in local healthcare centres" – Scott Lingley, "Lab-on-a-chip tests ready for clinical testing" *Express News* (20 September, 2005); There are several tests at the U of A that have been adapted to the lab-on-a chip device. These include, a "genetic test involving childhood lymphocytic leukemia."... [ a test ] "looking for chromosomal abnormalities in molecular myeloma and follicular lymphoma", [ a test in order to] "detect high viral loads in urine samples", Scott Lingley, "Lab-on-a-chip tests ready for clinical testing" *Express News* (20 September, 2005)

[237] Lingley, ***Supra*** note 236.

[238] Global Watch Mission Report, *Point of Care Diagnostics: The Way Forward – A Mission to California* (Report of a DTI Global Watch Mission, April 2004) at 19. Online: BIVDA,< http://ww.bivda.co.uk/.../Mission%20Report. pdf?DType=DocumentItem&Document=Mission%20Report.pdf ->

[239] ***Ibid.*** at 19-20.

[240] ***Supra*** note 238 at 19-20.

for multiple, potentially surprise results, be done in a clear, concise and thorough manner that ensures a legitimate consent procedure?

Following from the discussion of technical characteristics is a short summary of the technologies benefits. Noteworthy are arguments that the lab-on a chip technology has benefits that will outweigh the disadvantages.[241] For example, these nanotechnology chips are capable of producing "rapid, standardized, automated results" in a "cost effective way".[242] Cost cutting measures are exhibited through the utilization of smaller samples (which is of advantage in intensive care situations), a shorter "analysis time", and "higher levels of throughput and automation."[243] Rapid results have been deemed of aid in near patient and point of care testing.[244] As a result, the speedy and inexpensive nature of such testing could be of great economical service within the health system.

Numerous advantages of the microfluidic device or microchip include the decreased usage of expensive reagents and characteristics of "integration".[245] Some forms of these chips can possibly aid in "cancer or microbiology diagnostics, genotyping, gene expression, pharmacogenomics and environmental control".[246] The capabilities are far reaching and numerous.[247] For instance, DNA, RNA and proteins in

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[241] Bev Betkowski, "Nanotechnology sparks ethical questions" *Express News* (28 November 2003)

[242] Linda Pilarski, "Keynote Speaker Bio" (2005 Joint Conference of the CSTM,CBS, and Hema-Quebec, 21-24, April, 2005) Online:<http://www.transfusion.ca/new/meetings/2005/pilarski-bio.html>

[243] Vijay Srinivasan, Vamsee K. Pamula & Richard B. Fair, "An Integrated digital microfluidic lab–on-a-chip for clinical diagnostics on human physiological fluids" (2004) 4 Lab Chip 310 at 310.

[244] ***Ibid.*** at 310.

[245] Yao Zheng, "Rapid Self Assembly of DNA on a Microfluidic Chip"(2005)3:2 Journal of Nanobiotechnology at 2.

[246] M. Cuzin, "DNA Chips: a new tool for genetic analysis and diagnostics"(2001) 8 Transfus Clin Biol (2001)291 at 291

[247] According to Koehne, "A fusion of micro- and nanotechnologies with biology has great potential for the development of low-cost disposable chips for rapid molecular analysis that can be carried out with simple handheld devices." - Jessica E. Koehne et al., "Miniaturized Multiplex Label-Free Electronic Chip

the blood can be evaluated quickly and efficiently.[248] In concert with the aforementioned advantages, the sophisticated diagnostic tests provided via these technologies will increase precision and more importantly play a preventative role in medicine.[249] This is reinforced by predictions that new technologies in biotechnology and nanotechnology will enable the "emergence of a forecast, prevent and manage paradigm".[250]

## 3. The Emerging Policy Challenges in Canadian Health System

### (i) Introduction

In evaluating policy, it is essential to point out novel challenges that medical diagnostics create, including commercialization challenges.[251] Noteworthy are challenges that are exacerbated by a lack of knowledge about novel products and procedures in the clinical environment.[252] Similarly, it has been expressed that if legal and ethical issues are not addressed, (for instance in patent law) "it may actually impact the commercialization process".[253] Interestingly, it is the "commercialization of the invention or the use to which it may be put which raises the social and ethical

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for Rapid Nucleic Acid Analysis Based on Carbon Nanotube Nanoelectrode Arrays", (2004) 50 Clinical Chemistry 1886 at 1886.

[248] Geoff McMaster, "National Award for Oncology Star" *Express News* (22 April 2002)

[249] ***Supra*** note 229 at 41.

[250] "New Technologies in Medicine: Biotechnology and Nanotechnology" *Disease a Month* (November 1999) at 454.

[251] Dr. Robert Melhalso lists a number of challenges in "commercialization of micro/nano-based healthcare products". The points include: "lack of effective intellectual property and know-how transfer from research to engineering and production, lack of design engineering education in small technologies, lack of metrics, standards, and specifications, lack of a depository of knowledge, lack of an available infrastructure for selection of micro/nano fabrication and assembly approaches; lack of an available capability to build prototype, pilot and production quantities, challenges of marketing new paradigm products, challenges of regulatory and insurance control, challenges of educating doctors and consumers on advantages and uses of new health care products" – Melhalso, ***Supra*** note 11.

[252] ***Supra*** note 14.

[253] Deborah Komlos, "Tough issues in Genomics – GELS comes to the fore" *Biotechnology Focus* (1 February, 2004)

concerns".[254] Thus, supporting the necessity for examining these challenges is the knowledge that "medical diagnostics are inextricably linked to the future development of health care".[255] As such, it is a timely and relevant addition to evaluate the effects of such diagnostics in the clinical setting. This introductory section will give a broad overview of nanotechnology policy challenge within the healthcare system. The latter section will look at specific areas of health law that are of pressing concern in doctor-patient relationships.

(ii) Patent & Health Policy Challenge

It has been pointed out that patent law was not designed for social, ethical concerns[256], for example, health policy discussions. However, such innovation warrants an investigation of the broad picture. It has been argued that "health and safety are not, and never have been, the preoccupation of intellectual property legislation".[257]Although it is pointed out in *Harvard College v. Canada* (Commissioner of Patents)[258] that the importance of patents in financing innovation is essential, one distinction is drawn that what is beneficial is not "necessarily patentable".[259] As such, there are a number of conflicts at the intersection of health and patent policy. Primarily, I note concerns regarding how and where the products of nanotech will be distributed and utilized.

As has been noted in the case of biotechnology, two pressing issues relevant to patenting are the "equitable distribution of the products of … research" and "ensuring

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[254] Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues* - Executive Summary
[255] MANCEF, "Commercialization of Medical Diagnostic and Other Devices" (Euronanoforum, 5 September , 2005)
[256] ***Supra*** note 225.
[257] *Harvard*, ***supra*** note 36 at II 82(QL).
[258] *Harvard*, ***supra*** note 36.
[259] *Harvard*, ***supra*** note 36 at II 18.

fair access to those products".[260] Of particular interest to the case of nanomedical products is the case of access to new forms of genetic testing through the public system and the presence of the nanodivide[261]/equity issue. As such, the intersection of patent and health care policy in such novel circumstances is a source of significant challenge.

First, I discuss the question of access to such technologies. As past patent infringement claims by Myriad Genetics in association with their genetic tests for BRCA I & II illustrate[262], public access to such novel technologies is not guaranteed. There have been calls for reform to patent laws in the case of genetics in order to "fit societal needs for both innovation and affordable access to these innovations."[263] Unfortunately, this access can logistically be challenged on several fronts:

> Nanotechnology patents in the biomedical field could also deter useful and life-saving research as well if several different patented nanotechnology patents are required to continue research. A person could even be prevented from receiving a treatment if the company decides not to license the life-saving patented service at all. [264]

In creating policy that will preserve the health care system present in Canada today, I note several issues previously encountered in gene patenting and genetic testing in order to aid in policy formulation. Vigilance is necessary as one considers the radiating effects of such innovations. It is argued that Canadian patent policy should

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[260] Lori Sheremeta and E. Richard Gold, "Creating a Patent Clearinghouse in Canada: A Solution to Problems of Equity and Access", (2003)11 Health law Review 17

[261] Equitable distribution of beneficial products of nanotechnology

[262] Myriad genetics has U.S. and Canadian patent on BRCA1 and BRCA2 genes (Breast cancer and ovarian cancer genes). Myriad attempted to enforce patent rights against publicly funded labs that performed these tests in Canada. Different Provinces have reacted differently to demands - ***Supra*** note 260

[263] Donald J Willison &Stuart M. Macleod, "Patenting of Genetic Material: Are the benefits to Society Being Realized?" (2002)CMAJ 167(3)

[264] Chicago-Kent College of Law - Institute on Biotechnology and the Human Future, Online: http://www.thehumanfuture.org/topics/nanotechnology/policy.html Last accessed: November 14, 2005

"strike an appropriate balance between public and commercial interests".[265] For instance, as is noted in biotechnology, it is important to preserve a patent's "economic benefits" while at the same time ensuring proper "access to healthcare".[266] In fact, there have been calls for patent reform to be made a part of the health reform agenda.[267] Illustrative are examples of gene based diagnostics, where questions are posed such as, will early patents make these tests expensive[268] or increase the likelihood that the public health will be serviced in a timely fashion? Since patents provide a monopoly, the inventor can, to a large degree control access to price in Canada's system.[269]

The second important concern that is of novel interest is that of the nano-divide. Equitable distribution in nanotechnology is often termed as the nano-divide.[270] This is not a new issue, as it has also been compared to the similar societal experiences of a "genomics divide".[271] Many of these discussions on nano-divide, link largely to benefits that may not be seen in the developing world. A contrary point of one academic indicates that many of these new technologies are available in the "1/3" world at a cost that citizens can use.[272] However it has been clearly pointed out that many new and

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[265] Ikechi Mgbeoji & Byron Allen, "Patent First Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Health Care and Biomedical Research" (2003) 2 Canadian Journal of Law & Technology 83 at 87.

[266] ***Supra*** note 216 at 28.

[267] Developing accurate and economical diagnostic tests is obviously in the public interest...[govt should] consider patent reform as part of its health-reform agenda, and get to work." - Gene patent Policy review urgently needed *Edmonton Journal* (10 January 2003) Online:< http://lists.essential.org/pipermail/ip-health/2003-January/004063.html> Last accessed: July 29, 2005.

[268] Sandy M Thomas, "Intellectual Property Rights and the Human Genome", in Timothy A. Caulfield & Bryn Williams Jones, eds., *The Commercialization of Genetic Research – Ethical, Legal & Policy Issues,* (New York: Kluwer Academic/Plenum Publishers, 1999) at 61.

[269] ***Supra*** note 218 at 16

[270] ***Supra*** note 1 at 41 ; Heidi Kingstone, "The Nano-State is Coming" *Saturday Star* (28 May, 2005) 14.

[271] ***Supra*** note 27 at R11.

[272] Professor Shervanthi Homer-Vanniasinkam, " Nanotechnology-Promising a Revolution in Health Care" (Public Debate, Euronanoforum 5 September 2005)

developing technologies/treatments that would be of valuable use[273] may not be effectively distributed.[274] Arguments may be made for a clarification of the healthcare/patent intersection when discussing the products of nanomedicine.

## 4. Legal Challenges Associated with the Clinical Application of Novel Technologies

This chapter now turns to the basic health law challenges that may emerge as a result of nanotech, specifically regarding the use of microfluidics and nanofluidics in the clinical setting. Notable is that previous challenges associated with emerging biotechnologies in the clinic are amplified. For example, problems surrounding genetic counseling, genetic testing and screening, and genetic discrimination are persistent in this scenario.[275] Legal issues of informed consent and confidentiality will be the focus of this discussion.[276] For the purposes of this paper an overview of the current state of

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[273] According to Mnysiwalla et al, the advantages include "Possible novel methods of aid include, safer drug delivery, lower needs for energy, cleaner energy production, environmental remediation, and better prevention, diagnosis and treatment" - ***Supra*** note 27 at R11

[274] It is also important for us to consider equitable distribution of beneficial technologies within our own country. For instance, such potential is shown through the push towards privatization in the province of Alberta. A key issue that will arise is whether these tests will, in fact, be covered by the public system. That is, will tests be deemed "medically necessary." - Timothy A. Caulfield et. al, "Providing Genetic Testing Through the Private Sector : A View from Canada" (Autumn 2001) ISUMA 72; Numerous commentators have noted the challenges associated with evaluating new technologies. For example, in the *Commission on the Future of Healthcare in Canada,* the importance of ensuring there is a thorough and independent technological assessment is noted. - *Report on the Commission on the Future of Healthcare in Canada – building on Values: The Future of Healthcare in Canada* (Ottawa: Canadian Government Publishing Communication Canada) Similarly, there are important social values to be considered - *Chaoulli v. Quebec (Attorney General)* 2005 SCC 35

[275] ***Supra*** note 223 at 75.

[276] In order to paint a clear picture of the landscape as it exists today one must evaluate some of the other well known policy challenges that still do currently exist. Genetic testing has always been a very controversial area and the management of this type of information a source of animated debate. The differentiation of genetic information has been hotly debated and strong arguments exist on either side. A short summary of the situation is warranted given the pointed personal information that these new technologies will uncover. The debate over genetic testing includes arguments that genetic tests are different than other medical testing that does not involve DNA. This line of thought is known as genetic exceptionalism. - Nuffield Council on Bioethics, *Pharmacogenetics Ethical Issues* (London : Nuffield Council on Bioethics, September 2003) at xiii Online: www.nuffieldbioethics.org; It should be pointed out that one of the regulatory challenges in dealing with genetic results is defining what actually

the law is given, followed by a consideration of hypothetical adjustments and potential variance in policy to deal with the products of this new nano – era.

(i) Informed consent

The consent of the patient is needed before any treatment takes place. Informed consent involving "full disclosure" is a "legal manifestation" of the ethical concept of "autonomy".[277] It arises from the need to respect "individual autonomy" in healthcare decisions.[278] Consent must be "voluntary", the individual consenting must have proper "capacity", the consent is specific to the individual conducting the treatment and for the specific treatment agreed upon, and the consent must be informed consent.[279]The Supreme Court Case of *Reibl v Hughes*[280] remains a seminal decision that created the standard of disclosure as being information that the "reasonable patient" would want to know and adopted a modified objective test of causation, ("would a reasonable person in the plaintiff's position have declined (or delayed) the treatment if properly informed? "[281] The court in *Riebl v Hughes*[282] termed the information that must be conveyed as

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constitutes genetic information. - Trudo Lemmens & Lisa Austin, "The Challenges of regulating the use of genetic information" (2001) 2 ISUMA at 2.

[277] Timothy A. Caulfield & Diana E. Ginn, "The High Price of Full Disclosure: Informed Consent and Cost Containment in Health Care"(1992) 22 Manitoba Law Journal 328 at II 4.

[278] Erin Nelson, Katrina Haymond, & Mona Sidarous, "Selected Legal and Ethical Issues Relevant to Pediatric Genetics", 6 Health Law Journal (1998) 83 at II 3;

[279] Nelson et. al, ***Ibid.*** at II 6. According to Dickens & Cook, "Modern law has added an important refinement to the principle of patients' consent, by requiring that any consent be adequately informed…part of practicioners' legal duty of care, under the law of negligence, is now not simply to perform procedures with due skill, but also to ensure that their patients have understood enough about treatment choices and the implications for them of each option."- Bernard M Dickens & Rebecca J. Cook, "Ethical and legal issues in reproductive health – Dimensions of Informed Consent to Treatment", 85 International Journal of Gynecology and Obstetrics (2004) 309 at 309-310.

[280] Reibl v Hughes(1980), 114D.L.R.(3d) 1 (SCC); Gerald Robertson at. al, "Legal Norms Relevant to the Practice of Human Genetics: A Background Paper"(1995) 3 Health law Journal 187-211 at II10.; E. I., Picard, & G. B., Robertson, Legal Liability of Doctors and Hospitals in Canada, 3rd Ed. (Toronto: Carswell Legal Publications, 1996); Jocelyn Downie, Timothy Caulfield & Colleen Flood eds. *Health Law & Policy* (Markham:Butterworths May 2002)

[281] Gerald B Robertson, "Informed Consent 20 Years Later" (2003) Health Law Journal Special Edition at 153-154.

any "material, special, or unusual risk".[283] The duty to disclose has become more onerous than in *Reibl v Hughes.*[284] It includes any information that a reasonable person in the patients position would want to know. The case of *Ciarlariello v Schacter* [285] stated that the duty is with the physician to "show that the patient comprehended the explanation and instructions given".[286]

The informed consent model has generated controversy in recent years due to the complex, evolving nature of genetics. Sharpe argues that the model of informed consent now present in Canadian courts is different from a "genetics model of informed consent" that has evolved over time.[287] It has been argued that in the field of genetics it will be increasingly difficult for physicians to "fulfill informed consent obligations" because of the wide range of genetic information.[288] The "material information" that must be divulged, includes "medical and non medical considerations", that is side affects as well as social consequences of treatment.[289] The following is an overview of pertinent issues:

> Obtaining informed consent to genetic testing is particularly challenging in view of the complexity of genetic information,...and the social and psychological implications of testing. Positive genetic test results are rarely accompanied by the prospect of either treatment or cure. In the absence of effective treatment, the

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[282] Reibl, ***Supra*** note 280.
[283] Bernard M. Dickens "Informed Consent" in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds. *Health Law & Policy* (Markham:Butterworths May 2002) at 131.
[284] ***Supra*** note 281 at 155 - Points to consider are that remote risks are considered material, all material information must be disclosed including "alternative treatments", there is a duty to ensure a patient understands the information. (for example information cannot be too technical).
[285] *Ciarlariello v Schacter* [1993] 2 S.C.R. 119
[286] Jocelyn Downie et. al., ***supra*** note 280 at 144.
[287] Neil Sharpe, "Reinventing the Wheel? : Informed Consent and Genetic Testing for Breast Cancer, Cystic Fibrosis, and Huntington Disease"(1997)22 Queens Law Journal 389 at 7 (QL).
[288] Timothy Caulfield, "Gene Testing in the Biotech Century: Are Physicians Ready?"(1999) 9 CMAJ 1122 at 1123.
[289] Barbara Von Tigerstrom et. al , "Legal Regulation of Cancer Surveillance"(2000) 8 Health law Journal (2000) 1 at II 31 (QL).

> potential for psychological harm and social discrimination must be considered.[290]

The application of nanotechnology will amplify these challenges. In the context of microfluidics many of these new issues relate to the impact on consent of instantaneous, multiplexing[291] tests and pharmacogenetics.[292]

How will the common law doctrine of informed consent withstand these challenges? For example, what information will be deemed material? How does a physician determine what is material information in the case of an instantaneous test, garnering uncertain, unknown, comprehensive results? As has been illustrated before, many genetic tests convey different types of information. For example, some results could be polygenic[293] and probabilistic, some could be monogenic[294] and determinitive.[295]Unlike many current testing technologies genetic testing will only

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[290] Michael M.Burgess et. al, "Bioethics for Clinicians: Ethics and Genetics in Medicine" (1998) 158 CMAJ 1309 at 1310.

[291] Multiplex genetic testing is genetic testing for two or more completely different conditions in a single testing session. For instance, one could immediately be told that they have a number of genetic issues at once. Concerns include how to group these tests allowing for the proper "pretest education, counseling, and consent." There are arguments over whether informed consent is required for each test on the panel. Since these results can immediately affect insurability and employability, it makes achieving adequate consent near impossible. NY State Department of Health, Genetic Testing and Screening in the Age of Genomic Medicine Online: http://www.health.state.ny.us/nysdoh/taskfce/screening.htm;

[292] Similarly we should look at relevant aspects of pharmacogenetics (the"study of genetic differences between individuals in their response to medicine.") - *Pharmacogenetics, **supra*** note 276 at xiii.
Other consent concerns include that the test "may reveal information that is unrelated to the illness in question, or indeed to any disease, and that this additional information may not be known at the time the sample is taken. This makes obtaining informed consent to the test difficult" - *Pharmacogenetics, **supra*** note 276 at xxi; For relevant reading on pharmacogenetics see: X. Steve Fu et. al, "Cancer Genomics, Proteomics, and Clinical Applications" Online:<http://binary.engin.brown.edu/publication/clinic.pdf> ; Barbara Evans, David Flockhart, & Eric Meslin, "Pharmacogenomics, has the potential to spark a major, technology driven restructuring of the health care and pharmaceuticals industries", *News Medical Net* (21 December, 2004) Online:< http://www.news-medical.net/?id=6979>

[293] Polygenic - "a genetic disease caused by the combined actions of two or more genes" - http://www.medterms.com/script/main/art.asp?articlekey=4987 Last Accessed: September 26, 2005

[294] Monogenic – "pertaining to one gene" - http://www.medterms.com/script/main/art.asp?articlekey=21822 Last Accessed: September 26, 2005

[295] Patrick S Florencio, "Genetics, Parenting, and Childrens rights in the twenty –first century" (2000) 45 McGill Law Journal 527 at II 38; Monogenic & deterministic tests convey a greater chance of harm, Bryn

provide probabilistic information about the possible predisposition to future health concerns. Only testing for monogenic diseases such as Huntington's, are relatively determinitive. As such, it is a constant challenge to evaluate the degree of risk and to communicate that risk in genetic testing given that the predictive value varies.[296] Also variable are "risk factors" associated with the disorders and the "statistical reliability" of the tests.[297] This discussion of risk and consent is further complicated by a consideration of the speed and relative management of emerging nanotech testing procedures.

Much of the past debate about consent in the context of genetic testing dealt with tests where there was a delay between testing and results. Also the test often took place at a specific genetic clinic (or research facility). This allowed for the implementation of specific "genetic" consent procedures including genetic counseling. The previous discussion of the science illustrated how these genetic tests are technically different from what has been experienced before now. One should evaluate the logistics of genetic counseling in this context and the subsequent garnering of adequate consent in these circumstances. At the same time one should be mindful of arguments that the "requirements for informed consent are or ought to be distinct" in genetic counselling.[298]

In examining the situation, a quick review of how genetic counseling is viewed is necessary. It is generally accepted that genetic testing is only done after an individual

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Williams-Jones, "Private Genetic Testing in Canada: A Summary"(2001) 9 Health law Review 10 at II 38.

[296] Trudo Lemmens, "Selective Justice, Genetic Discrimination and Insurance: Should We Single Out Genes in Our Laws?" (2000) 45 *McGill Law Journal* 347-412 at II 50.

[297] ***Ibid.*** at II 49.

[298] The Roeher Institute, *The Construction of Disability and Risk in Genetic Counselling Discourse* (North York: The Roeher Institute, January 2002) at 63.

partakes in genetic counseling.[299] Such training is provided by a number of associations and programs in Canada.[300] Genetic specialists such as counselors will be even more valuable as the cases become more "complex".[301] Literature has indicated that there is a "conceptual model"[302] of a genetic counsellor's duty of care. Academic commentary indicated that there has been consensus on the need for "comprehensive, non-directive, genetic counselling prior to genetic testing."[303]Other academics have deemed this method "unattainable".[304] Key to this discussion is whether genetic counselling can be adequately performed when test and results are instantaneously available.

In the past, jurisdictions have implemented policy indicating that the ultimate responsibility for the patient's case, including genetic counseling, lies with the physician.[305]As has already been mentioned, case law indicates that the informed consent duty lies with the physician.[306] Thus, it is legitimate to conclude that the primary care physician will be left with the responsibility for ensuring there is sufficient consent throughout. There are few Canadian cases in the area and only in the specific area of prenatal testing.[307] There are a number of individuals who can carry out genetic

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[299] ***Supra*** note 288 at 3.
[300] Mona Sidarous & Estelle Lamothe, "Norms and Standards of Practice in Genetic Counselling" (1995) 3 Health Law Journal 153 at II 37(QL).
[301] Francis S. Collins & Alan E. Guttmacher, "Genetics Moves into the Medical Mainstream", 286 JAMA (2001) 2322 at 2323.
[302] ***Supra*** note 298 at 59.
[303] Timothy Caulfield, "Genetics and the Law", (Health Law Institute) at 10
[304] A Clarke, "Is Non-directive Genetic Counselling Possible?" (1992)47(5) Obstet & Gynec. Survey 304 in John B Dossetor & Marion C.E. Briggs, "Genetic Counselling: A Role for Relational Ethics" (1995) 3 Health Law Journal 289-299 at II 4.
[305] Singapore Bioethics Advisory Committee, "Ethical, Legal and Social issues in genetic testing and genetics research" (Singapore : 5 april 2005) at 6.62 Online: < www.bioethics-singapore.org/ resources/pdf/GT%20CP%20Final.pdf>
[306] *Ciarlariello v Schacter* [1993] 2 S.C.R. 119
[307] *R v Hunter*(1996), 32 CCLT (2d) 44 (Ont Ct [Gen Div]); *Arndt v Smith* (1997), 148 D.L.R. (4th) 48 (S.C.C.)

counselling.[308] However, as a result of an increase in demand and a shortage of counselors the general practicioner is the most likely candidate to perform this task.[309] These thoughts are further complicated by arguments that while the family doctor's role in genetic counseling "is bound to increase", the doctor's preparedness to "deal with complex issues" is less than clear. [310] This focus on the primary care physician is in diametric opposition to policy recommendations that have reinforced the importance of genetic counseling being delivered by an individual who is adequately trained and informed.[311]

Previously results took time and laboratory results could take weeks before they were conveyed to the doctor. With the instantaneous results that nanotechnology can produce, how do doctors properly and immediately convey the risks and the results while adhering to all the ethical and legal responsibilities that they have as a physician? Previous queries posed included which tests would require counseling and whether the patient would feel increased pressure to get the test because of the speed and accessibility.[312]

Since these new tests bring with them definite concerns about the issue of timing and the obtaining of adequate consent, how does one utilize traditional practices of

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[308] It is recognized in policy documents that genetic counseling is performed in the United States by medical geneticists, Phd's and MSc (counselors) and Primary care physicians (who oddly enough have inadequate genetics knowledge). - Michel Revel, "Genetic Counselling" (Paris: United Nations Educational,Scientific and Cultural Organization, International Bioethics Committee: 15, December,1995) at 3
Online:< www.academy.ac.il/bioethics/articles/ GeneticCounselingUNESCOfullreportRevel95.pdf>;

[309] Neil Sharpe, "Reinventing the Wheel? : Informed Consent and Genetic Testing for Breast Cancer, Cystic Fibrosis, and Huntington Disease"(1997)22 Queens Law Journal 389 at 6 (QL).

[310] Joe T R Clarke, "Professional Norms in the Practice of Medical Genetics" (1995) 3 Health LJ 131-151 at II 33.

[311] ***Supra*** note 305 at 6.62.

[312] ***Supra*** note 229 at 43.

genetic counseling effectively in such situations? Conducting adequate counseling sessions is less than impossible and once consent is obtained, "on the spot" results will be there for the physician to evaluate and potentially convey to his or her client. The need for adequate time to digest and comprehend the implications has been extensively discussed:

> The timing of the discussion may prove to be a critical element. As noted, a patient's psychological responses can significantly impair comprehension. Although such responses may prove to be nothing more than part of the normal coping process, the geneticist must provide adequate time for the patient to proceed through these reactions. Premature discussion of genetic information may lead to misunderstanding, dissatisfaction, rejection of counseling, and aggravation of a patient's feelings of anxiety and despair.[313]

Policy documents recommended that the patient be given adequate time to understand the procedure that they will partake in.[314] *Ciarlariello v Schacter*[315] dealt with the withdrawing of consent and a renewal of consent for the continuation of a procedure. In this case interesting arguments including the argument that "consent is a process, not an instant in time" are useful for our purposes.[316] If time and effort must go into an adequate consent process, it is questionable how adequate consent will be achieved in a short doctor's visit, usually a matter of minutes given the potential of such testing. Arguably, suggestions for a reworking of the informed consent framework should incorporate issues related to genetic counseling, as well as the instantaneous and multiple results that are characteristic of such tests. The following section evaluates the situation and makes some preliminary suggestions.

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[313] Neil F. Sharpe, "Genetic Screening and Testing in Canada: A Model Duty of Care" 4 Health Law Journal (1996) 119 at II 27.
[314] ***Supra*** note 305 at 3.6.
[315] Ciarlariello ***Supra*** note 306.
[316] Ciarlariello ***Supra*** note 306 at II 46 (QL)

Policy Options – Informed Consent

It is arguable, according to the technicality of a multiplexing, instantaneous test that a reasonable patient may not comprehend the seriousness of the test they are about to undertake. The individual may feel pressure to undergo the test and feel overwhelmed. This is particularly problematic for those without support and in a susceptible position. Illustrative is the case of pharmacogenetics in which the patient may perceive a lack of choice as the test may be a prerequisite to participation in a clinical trial for medication the individual may need.[317] If a doctor is recommending a test and the individual is simultaneously experiencing health problems, the person may agree that this is the best avenue basing their decision on fear or apprehension. This increasing focus on doctor's responsibility brings to mind an interesting point in *Meyer Estate v Rogers.*[318] It was stated in that case "human nature being what it is, people tend to consent to procedures recommended by their doctors."[319]

The instantaneous and comprehensive nature of results warrants a reconsideration of informed consent standards. Primarily, suggestions should be made for a mandatory genetic counseling session regardless of how quickly the test can be proposed and completed. Second to this is a reconsideration of informed consent principles. It is essential that devastating social consequences are not unknowingly thrust upon those that may be instantaneously labeled as genetically deficient. Instantaneous or perceived emergency situations can lead to a complete collapse of now

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[317] Pharmacogenetics, ***Supra*** note 276 at 31.
[318] Meyer Estate v Rogers78 D.L.R. (4th ) 307
[319] ***Ibid*** at 318.

accepted informed consent procedures. No individual should be subjected to testing without being fully informed unless there is an obvious and immediate threat to that person's health. It becomes a complicated trade-off. It is questionable how a diagnostic procedure can be of service when an individual receives a positive result for a silent, unknown or untreatable illness. Upon receiving the positive result the individual is potentially uninsurable and results may affect employability.

The instantaneous and probabilistic nature of such tests, will not be adequately managed by current frameworks. This testing differs from diagnostic procedures that are prescribed, discussed and performed, with a delay offering ample opportunity for careful consideration, discussion and research. These issues are likely commonplace with respect to other diagnostic procedures that are quickly delivered. For instance, emergency rooms lend themselves to "instantaneous", non-threatening situations on a daily basis. There is an emergency exception to consent.[320] However, not all situations in an emergency room are life threatening. It is commonplace to uncover an unexpected and unanticipated result based on unrelated symptoms. A logical suggestion for instantaneous procedures could be framed as the "Instantaneous Judgement" Model of Informed Consent". This means that even though a procedure can be performed instantaneously the consent procedure may take longer.

(ii) Duty to refer

Similarly, amplified difficulties are also present in the duty to refer. The issue as to whether the doctor has a duty to refer when the subject matter is outside of his

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[320] Erin Nelson "The Fundamentals of Consent" in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds. *Health Law & Policy* (Markham:Butterworths May 2002) at 117.

expertise takes on a special meaning in the area of genetics. It has been illustrated in studies, that many in the physician population "have a poor understanding of human genetics."[321] A doctor who chooses not to refer may be presenting himself or herself as a "competent geneticist" and thus may be held to the "standard of care" of a geneticist.[322] Second to this we should note that arguments exist indicating that the duty of care of a geneticist is distinct from that of other physicians.[323]

Novel policy questions about expertise will arise in cases of duty to refer. Are doctors prepared to take on the genetic counseling themselves for tests that can produce such rapid, comprehensive results? For example, in deciphering multifactorial disease risk, the job of any genetic counselor is challenging because of the difficulty in determining if the disease is linked to contributions by genetic factors, environmental factors, or both.[324] The instantaneous, comprehensive nature of this nano testing is yet another complex hurdle for policy makers in this area. As such, pressing challenges that must be addressed in this discourse include the clarification of the acceptable level of expertise/knowledge for administering any given test. For example, the question of when a geneticist must be consulted must be clarified. Due to the complexity of results garnered through such testing, these questions are of utmost importance.

### (ii) Confidentiality & Warning Family Members

Increasingly important in this era of emerging technologies is how a physician views and conveys personal medical information. Novel technologies amplify the

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[321] ***Supra*** note 288 at 3.
[322] ***Supra*** note 298 at 59.
[323] ***Supra*** note 298 at 59.
[324] ***Supra*** note 310 at II 12; Sheila McLean & John Kenyon Mason, *Legal & Ethical Aspects of Healthcare*, (London: Greenwich Medical Media Ltd., 2003) at 149.

already controversial discussion. Again, the instantaneous, complex and uncertain nature of the results will affect the practices currently used to moderate such situations. Ideally, there are established rules about confidentiality and the nature of the doctor patient relationship.[325] Likewise, the duty of confidentiality arises through "tort, contract and equity, case law, statutes and ethical codes".[326]The Canadian Medical Associations *Code of Ethics* protects the patients right to confidentiality notwithstanding obligations under the law.[327] This duty is "echoed"[328] in other guidelines dealing with similar information, for instance, "respect for privacy and confidentiality is one of the essential *Tri-Council Policy Statement* ethical principles"[329]. There are also issues regarding whether our family members are adequately protected in the upholding of confidentiality rules. In Canada the duty to warn third parties is a source of continuing debate. For instance, there are questions regarding the warning of "a third party known to be at risk of AIDS or a genetic disorder"[330]. The "duty to warn" in family genetic dilemmas is "based on the premise that warning is needed to avoid serious harm."[331] There are a number of factors included

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[325]Jennifer Miller, "Physician-Patient Confidentiality and Familial Access to Genetic Information"(1994) 2 Health law Journal 141at II 4; As is written by Von Tigerstrom, "Fiduciary law compels those characterized as fiduciaries (e.g., physicians) to do that which is in the best interest of the beneficiary (e.g., patients)... Indeed, in the Supreme Court of Canada decision of McInerney v. MacDonald it was found that "[c]ertain duties do arise from the special relationship of trust and confidence between doctor and patient" and, therefore, physicians must "act with utmost good faith and loyalty" – ***Supra*** note 289 at II 34

[326]***Supra*** note 298 at 61.

[327] Mary Marshall and Barbara von Tigerstrom, Health Information in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds. *Health Law & Policy* (Markham:Butterworths May 2002) at 190.

[328] ***Ibid*** at 443.

[329] CIHR Draft Privacy Best Practice Guidelines.http://www.cihr-irsc.gc.ca/e/22095.html

[330] ***Supra*** note 327 at 201.

[331]***Supra*** note 290 at 1311.

in discussions on family and confidentiality.[332] In discussing whether one can violate confidentiality in order to warn, *Smith v Jones* [333] reconsidered the principle that a doctor has a duty to warn if their patient may cause harm to a third party,[334] which was enunciated in *Tarasoff v.Region of University of California.*[335] It has been expressed that the judge in *Smith v Jones*[336] should not have "gone down the Tarasoff road" as the torts case was of "limited usefulness" in the case of solicitor – client privilege". [337] In *Smith v. Jones*[338] the exception to confidentiality was seen to be acceptable in the case of "protecting public safety" and "preventing harm".[339]

Noteworthy is that lower courts in the United States have made several relevant rulings in the area[340]. As well, there are numerous privacy issues presented. As such, procedures on how these types of information are handled must be clarified. Seemingly, physicians need identifiable categories of harm or risk to aid them in classifying the

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[332] For example, "the duty of physicians and patients to inform or disclose genetic risk information to family members, family member's right not to know this information, and family members duty to collaborate in research" - Trudo Lemmens & Lisa Austin, ***Supra*** 276 note at 7.

[333] *Smith v Jones* [1999]1 S.C.R. 455 at 456.

[334] William S. Clark, "Duty to Warn and Confidentiality" (7 October, 2002) Online: < http://www.harpergrey.com/publications/pdfs/Duty_to_Warn.pdf>

[335] *Tarasoff v.Region of University of California* 551P2 2d 334 (1976)

[336] Smith , ***Supra*** note 333.

[337] Wayne Renke, "Case Comment: Secrets and Lives – The Public safety Exception to Solicitor – Client Privilege: Smith v. Jones" (1999) 37 Alta. Law Review 1045 at II 42(QL).

[338] Smith , ***Supra*** note 333.

[339] Bartha M Knoppers & Genevieve Cardinal, "Genetics and the Law" in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds. *Health Law & Policy* (Markham:Butterworths May 2002) at 450; The test has been expressed by Clark as follows: "first, is there a clear risk to an identifiable person or group of persons? Second, is there a risk of serious bodily harm or death? Third, is the danger imminent? Clearly if the risk is imminent, the danger is serious." Clark, ***Supra*** note 334; Also see, Bartha M Knoppers & Genevieve Cardinal, "Genetics and the Law" in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds. *Health Law & Policy* (Markham:Butterworths May 2002) at 450-451;

[340] In the Florida case of *Patel v Threlkel* 661 so.2d 278 (Fl. 1995)) the court ruled that a doctor "has a duty to warn a third party about a genetically inherited disease", and that the duty is fulfilled by telling the patient of "any genetic ramifications of the disease". In *Safer v. Estate of Pack*, 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1966), the New Jersey court ruled that duty to "directly" warn "third parties known to be at risk of avoidable harm from a genetically transmissible condition" exists for physicians - Gary N. McAbee, Jack Sherman, Barbara Davidoff-Feldman "Physicians Duty to Warn Third Parties About the Risk of Genetic Diseases"102 Pediatrics 1998, 140-141.

cases they see. The key difference that may arise from nanotechnology is that some of the risks/harms are not known or definable. Therefore, new limits as to what exactly a physician is responsible for communicating may have to be defined. The disease possibilities are limitless and the resources to handle these situations limited.

## 5. Conclusion

Chapter II illustrated that new dilemmas are an extension of issues previously encountered in the genetics arena. The potential of such diagnostic technology is unlimited and a source of great excitement. It is also a source of controversy and challenge within the legal world. The testing is advantageous from a preventative medicine viewpoint. Yet numerous challenges exist at the intersection of the health and patent system. As there are numerous uncertainties surrounding the administration of such tests, the nature of the testing may prove problematic in the commercialization of such technologies For instance, the ramifications of positive testing, the probabilistic nature of predictions, and the sensitive nature of the information are monumental quandaries when viewed from ethical, social and legal viewpoints. Specifically the physician – counselor dynamic must be resolved as it appears that instantaneous testing will not allow for sufficient counseling or referrals to a specialist. Finally, how a physician, counselor and patient view and convey information is problematic in both the case of informed consent and confidentiality given the uncertainty surrounding genetic information. It is unfortunate to realize that these issues probably will not come to the forefront until someone litigates the issue as a result of a detrimental loss or a devastating result that was not adequately conveyed in their specific situation.

# Chapter 4 - Areas of nanotechnology policy challenge warranting further investigation in Canada

This paper has examined in depth two very important areas of policy challenge relevant to nanotechnology in Canada. These areas are of relevance to the innovation process in Canada and have been cited as areas that would present as challenges to the commercialization of such technologies. This concluding section will briefly point out other areas of policy challenge that are presenting in Canada and abroad. These notes can serve as a basis for further NE3LS research as the issues become more effectively described and investigated in Canada.

## (i) Human – Machine Interactions

The incorporation of artificial materials into a living human being is of increasing concern. There are questions about violations of integrity, such as invading the body without "free and informed consent", and the "manipulation of mental capacities".[341] For instance, through such innovations there may be ways to enhance "human abilities."[342] Current work on "nanotags" could lead to production and use of devices to be placed in our bodies for identification.[343] The recent introduction and FDA approval of the "Verichip" is similar in nature.[344] It is argued that this chip is a threat to both

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[341] Goran Hermeren, "Nano Ethics Primer" (Paper prepared for Mar 1-2, 2004 meeting of the Directorate-General for Health and Consumer Protection of the European Commission, "Mapping out Nano-risks) at 99

[342] It has been noted that " The physical human body can be changed with NT. eg, using Nanobots to strengthen and build muscle, increase bone density, destroy fat cells, enhance vision, enhance mental capacity." - Nanotechnology Overview Online: <http://nanotech.techheadnews.com/overview.php>

[343] ***Supra*** note 341 at 99.

[344] One description of this technology includes that,"Silently and invisibly, the dormant chip stores a code — similar to the identifying UPC code on products sold in retail stores — that releases patient-specific information when a scanner passes over the chip. At the doctor's office those codes stamped onto chips,

"privacy" and "personal safety".[345] This is not a specific example of nanotechnology, but is an example of the types of technologies that have the potential to change our lives. These chips can be read from a distance and could potentially broadcast information such as medical history and financial information.[346] Relevant issues have been considered in Canada.[347]

### (ii) Longevity

Longevity has been discussed in the context of increased life span due to early diagnosis, new cures (better medicines), cell repair devices to prevent aging and development of new body parts.[348] These improvements create new issues such as increased population size[349] and a related "increased demand on natural resources".[350] Ethical issues that have been identified in the area of life extension and nanotechnology include issues related to genetic modification, overpopulation, poor health, and elitism.[351]

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once scanned, would reveal such information as a patient's allergies and prior treatments (Hannibal "FDA approves implanted RFID chip for humans" *Arstechnica,* 13 October 2004, Online:Arstechnica <http://arstechnica.com/news.ars/post/20041013-4305.html, Last Accessed: November 16, 2005

[345] ***Ibid.***

[346] ***Supra*** note 344.

[347] The nano-bio-info-cogno (NBIC) {the convergence of nanoscience, biotechnology, information technology and cognitive science} is an important area for further consideration. It is noted that Defence Research and Development Canada are monitoring these issues from a defence standpoint. – Convergence of technologies for Innovative Disruption Online: <http://www.drdc-rddc.gc.ca/publications/issues/issues16_e.asp> As well, there have been interesting studies into the effect of NBIC on health, well being, disease and disability - Gregor Wolbring, "Enhancement Medicine : The Final Frontier" (30 October, 2005)

[348] Moor & Weckert, ***Supra*** note 107 at 307.

[349] Moor & Weckert, ***Supra*** note 107 at 307.

[350] Nanotechnology Overview Online: <http://nanotech.techheadnews.com/overview.php>

[351] Chris Phoenix, "Nanotechnology and Life Extension", (2003), Online: <http://www.xenophilia.org/nano_life_extension.html>

## (iii) Privacy & Security

The area of security and nanotechnology is a predominant policy concern. On the upside, surveillance may indeed lead to a "more stable, secure world.[352] Privacy and surveillance brings the issue of the potential infringement of civil liberties to the forefront. Noteworthy are sociological opinions that deem such surveillance activities as creating "a society that functions as a "panopticon." [353] Key policy issues include, who will regulate the direction of research in "defensive and offensive military nanotechnology."[354] As has been previously mentioned, privacy and access to genetic information produced via new nano-enabled technologies is an important and relevant issue warranting further investigation. There are questions regarding "threats to individual privacy" if microfluidic platforms are utilized outside the clinic by insurance companies and employers.[355] Specific information garnered through testing measures while advantageous, can allow for differing social and psychological effects on individuals. Some testing methods may eventually be used to predict how much a person's health care will cost.[356] In concert with this, there are accusations that these

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[352] ***Supra*** note 108 at 14.

[353] Michael Mehta, "On Nano-Panopticism: A Sociological Perspective" Online: http://chem4823.usask.ca/~cassidyr/OnNano-Panopticism-ASociologicalPerspective.htm. According to Mehta, A Panopticon is an institutionalised and physical form of surveillance. He also argues that the lab on a chip creates differing forms of panoptic effects. He argues for stronger laws for privacy and consideration of re-writing ethical codes of conduct.

[354] Supra note 27 at R11; Nanotechnology applications are of major interest to Defense and Homeland security in the U.S. For example, Coleman speaks of semiconductors, sensors and nanofabrics.- Kevin Coleman, "Nanotechnology and the Fight AgainstTerrorism"(2003)Online: http://www.directionsmag.com/article.php?article_id=375&trv=1&PHPSESSID=979cd2d744db0f3d230a8aa3831d3782> Figuring more predominantly in the dialogue is the possibility of a "nanotechnology arms race", - ***Supra*** note 1 at 41.

[355] Michael D. Mehta, "The Future of Nanomedicine Looks Promising, But Only if We Learn From the Past" (2004)13 Health law Review 16 at 18.

[356] Trudo Lemmens, "Selective Justice, Genetic Discrimination and Insurance: Should We Single Out Genes in Our Laws?" (2000) 45 *McGill Law Journal* 347 at II 6 – II 7.

technologies may create a "new dimension of eugenics"[357] or a "genetic proletariat".[358] It has been argued that "the tools of eugenics" have never been "more readily available".[359] Similarly, an editorial concerning the diagnostic gene chip expresses that such technologies are quite beneficial, but also possess capabilities for "serious abuse".[360] These problems identify and clarify the need for specific measures to prevent the mishandling of such sensitive information. Frameworks to support such novel techniques and circumstances should be evaluated prior to implementation of said technologies.

### (iv) Genetic Testing Outside of the Clinic

An issue that warrants further policy consideration is the availability of these tests outside of the clinic. As has been expressed in this context, physicians may "find a much more informed populace coming to their doorstep".[361] In fact, there has been speculation over the potential for an entire new health industry.[362] Interesting are the issues surrounding informed consent that arise in the case of *Hollis v Dow Corning Corp.*[363] It is possible that these issues may present themselves in this new field of testing. Arguments are made that "the principles underlying the doctrine of informed consent are equally, if not more, applicable to the relationship between manufacturers of

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[357] Wolfram Henn, "Genetic Screening with the DNA Chip: a new Pandora's Box?"(1999) 25 Journal of Medical Ethics 200 at 200.
[358]Shauna Labman, "Genetic Prophecies: The Future of the Canadian Workplace" (2004) 30 Man LJ 227 at II 1.
[359]Timothy Caulfield & Gerald Robertson, "Eugenic Policies in Alberta: From the Systematic to the Systemic"(1996) 35 Alta. Law Review 59 at (15 QL.)
[360]George S. Robinson, Editorial, Darwin in the Age of Biotechnology, *Cosmsos Journal* (2000) Online: http://www.cosmos-club.org/journals/2000/robinson.html> Last accessed: November 14, 2005
[361] Mark K. Anderson, "Dreaming about Nano-Healthcare" *Wired News* (14 November 2000) Online: <http://wired-vig.wired.com/news/technology/0,1282,40166,00.html>
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[363] *Hollis v Dow Corning Corp.*, 129 D.L.R.(4th) 609

medical products and consumers than to the doctor-patient relationship".[364] Given the preliminary concerns that exist over these tests being used outside the doctor-patient relationship, a whole new body of litigation could arise between manufacturers and patients. A survey of microanalytical devices such as "microchips", "gene chips" and "bioelectronic chips" was conducted in which conclusions were drawn that such clinical testing would eventually shift from the lab to "nonlaboratory setting".[365] There have been calls for a legislative ban on the possibility of over the counter genetic testing, however, it is also argued that if such testing takes place that genetic counseling be mandatory.[366]

## (v) Environment

Environmental questions are quite prevalent in a discourse on nanotechnology.[367] In considering policy challenge, examples of novel environmental issues should be noted. Examples of questions posed in the literature include, where do nanomaterials such as fullerenes and carbon nanotubes go "when they enter the environment" and what are the resultant effects?[368] A number of issues that have been encountered and documented in relation to nanotechnology have to do with the toxicity of new nano-

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[364] *Hollis, **Ibid.*** at II 25.

[365] Bernhard H. Weigl, Ron L. Bardell, & Catherine R. Cabrera, "Lab-on-a-Chip for Drug Development"(2003) 55 Advanced Drug Delivery Reviews 349 at 350.

[366] Human Genetics Alert, Dr. David King, Consultation Response to Human Genetics Commission Consultation on Marketing Genetic Tests (9 October 2002)Online:< http://www.hgalert.org/topics/geneticshealth/otcfinal.html

[367] There have been a number of studies examining the effects of nanomaterials. For instance, one study by Oberdorster, illustrated that uncoated fullerenes can cause oxidative damage to the brain in an aquatic species of bass - Eva Oberdorster, "Manufactured Nanomaterials (Fullerenes C60) Induce Oxidative Stress in Brain of Juvenile Largemouth Bass", (2004) 112(10)EHP 1058 at 1058. Online:EHP http://ehp.niehs.nih.gov/members/2004/7021/7021.pdf
Important to point out is that these results are not conclusive or immediately transferable to humans.

[368] ***Supra*** note 27 at R11.

substances. Most predominantly, the causes for concern are untested nano-versions of long known micro versions that display different properties because of their change in size.[369] Another area of interest is that of biological and chemical weapons and whether nanotechnology products would fall within existing treaties.[370]

### (vi) Charter Issues

A brief look at the constitutionality of regulating science is warranted as was done in the context of non-reproductive human cloning in a paper by Billingsley and Caulfield.[371] For instance, issues that arise in the discussion of genetics testing and nano include Charter issues such as scientific freedom, liberty, the right to health care and the right not to be denied health care.[372] Of course, it is important with subject matter such as nanotechnology to look at the "relationship between scientific freedom and the legislative prohibition of scientific research".[373] Since Canada currently does not have regulations dealing specifically with nanotechnology, scholars must deal with the hypothetical situation of an absolute legislative prohibition on nanotechnology research and development, specifically molecular manufacturing and whether this would violate freedom of expression under the Charter.[374] I have covered in this paper some of the scientific benefits of nanotechnology along with the social and ethical concerns.

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[369] ***Supra*** note 1 at 39.

[370] Glenn H. Reynolds, "Environmental Regulation of Nanotechnology: Some Preliminary Observations"(2001) 31 ELR 10681 at 10684; Toxicity is a key concept to the discussion.- Ron Dagani, "Nanomaterials: Safe or Unsafe?"(2003) 81 Chem & Eng News 2 Online: Chemical & Engineering News, at 2 http://pubs.acs.org/isubscribe/journals/cen/81/i17/html/8117sci2.html>;

[371] Barbara Billingsley & Timothy Caulfield, "The Regulation of Science and the Charter of Rights: Would a Ban on Non- Reproductive Cloning Unjustifiably Violate Freedom of Expression" (2004) 29 Queens Law Journal 647at 648.

[372] Timothy Caulfield & Colin Feasby, *The Commercialization of Human Genetics in Canada: An Overview of Policy and Legal Issues* in Bartha Maria Knoppers, ed, *Socio-Ethical Issues in Human Genetics* (Cowansville, Quebec: Les Editions Yvon Blais Inc, 1998) at 387-399

[373] ***Supra*** note 371 at 650.

[374] Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982, being schedule B to the Canada Act 1982 (U.K.), c.11 (s.2(b))

Discussing what the Charter implications would be if, in fact, the right to pursue these new avenues of research and development was taken away, is beyond the scope of this paper.

## Chapter 5 - Conclusions & Recommendations

This paper examined a number of relevant nano policy issues in the Canadian legal environment. Further in depth studies of existing legal regulatory frameworks are required. Such studies require a multidisciplinary team of researchers. Noteworthy, of course, is that these types of studies cannot be undertaken without adequate support and funding from government. The following list includes recommendations that should be of service in the policy making process.

Summary of recommendations:

(i) Create special prior art search strategy for nanotechnology by coordinating prior art search strategies with other jurisdictions;

(ii) Consider incentives to recruit expert nanotech personnel;

(iii) Create multidisciplinary examiner teams to allow for the most effective evaluation of nanotech;

(iv) Create an official classification category for nanotechnology as is seen in the United States;

(v) Evaluate effects of improvement concept on patentability[375];

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[375] That is, could a lot of nanotech patentability focus on improvements?

(vi) Modify existing structures to allow an exception for harms/consideration of pressing social policy concerns (eg. utilization of an idea similar to that of ordre public);

(vii) Define and clarify different categories of self replicators in terms of harm (bio, nano, nano-bio);

(viii) Implement experimental use exemption ;

(ix) Reconsider patents on methods of medical treatment;

(x) The instantaneous and comprehensive nature of clinical results warrants a reconsideration of informed consent standards - A logical suggestion for instantaneous procedures could be framed as the "Instantaneous Judgement" Model of Informed Consent", that is, a longer consent process for a instantaneous procedure where circumstances warrant;

(xi) A reconsideration of the causation standard in informed consent[376], for instance should the test be narrowed in the case of an instantaneous testing situation;

(xii) Clarify the acceptable level of physician expertise/knowledge for any given test;

(xiii) Clarify proper circumstances in which to consult a geneticist;

(xiv) Create identifiable categories of harm or risk to aid physicians in classifying the cases they see. [377]

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[376] Given statements such as that in Meyer Estate v Rogers78 D.L.R. (4th ) 307 where it was noted that "human nature being what it is, people tend to consent to procedures recommended by their doctors." Given the instantaneous nature of test would a reasonable person decline or delay?

[377] The key difference with this new technology is that some of the risks/harms are not known or definable. In this case we may have to define new limits as to what exactly a physician is responsible for communicating. The disease possibilities are limitless and the resources to handle these situations limited.

This paper covered two key areas of relevance to the innovation process in Canada. Interrelated themes of clinical challenge and patent policy serve as reminders of the challenges that exist in improving our systems of health & innovation. The first part of this paper examined patenting issues relevant to nanotechnology. The practical challenges created could arguably be contained with implementation of some important recommendations. An attempt has been made to point to some of the policy challenges that will no doubt be present in future. Nanotechnology at the Supreme Court of Canada may be far off, but as in the case of Harvard Mouse, valuable insight is garnered from policy-making bodies. Preemptive discussions surrounding nano-replicators will enable informed decisions on complex topics.

The broad policy issues that confound the latest example of cutting edge genetic research have also been considered in this paper. The discussion of genetic diagnostic technologies is not new. However, in considering policy challenge, consideration must be given to the novel circumstances that do present in the nano-enabled version of such genetic diagnostics. As many of these products are rapidly reaching the commercialization stage, pressing concerns held by patient and doctor must be addressed. The challenges on health systems must be considered and have been discussed in other countries.[378]

Currently there is little information provided in Canada with respect to nanotechnology, law and policy. Thus identifies a need for further investigation.

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[378] According to Campitelli, there is a "challenge to transform health systems from intrinsically reactive to proactive". – Dr. Andrew Campitelli , BioMNT, MiniFab "Integration of bio, macro, nano, and information technology for medical diagnostic systems: challenges and opportunities" (Presentation to Euronanoforum, Edinburgh 5-9 Sept)

Canada must be diligent in pursuing some of the initiatives suggested for similar technologies. As well, there are lessons to be garnered from work done in other jurisdictions. Notable is that there are continuing calls for some sort of international regulatory framework and multinational research infrastructures.[379] As Canada puts its policy positions in order, increased cooperation and opportunity on an international level should be possible. Inevitably, research and development will continue and government must be diligent in promoting innovation while at the same time preserving the health and safety of its citizens.

[379]According to Caulfield, important reasons for looking at international regulation include forum shopping. As well, the differing religious and political climates make reaching a consensus difficult The case of genetics is transferable to the current situation where it is argued that if we want to ensure "safe application" of technologies there must be common agreements between different jurisdictions- ***Supra*** note 21

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